Garwin Gerstein & Fisher LLP
Bruce E. Gerstein, Esq.
88 Pine Street
New York, NY 10005
(212) 398-0055
bgerstein@garwingerstein.com

Attorneys for Plaintiff and the Proposed Class

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

J M SMITH CORPORATION d/b/a, SMITH DRUG COMPANY, on behalf of itself and all others similarly situated, Plaintiff, v. ACTAVIS, PLC, FOREST LABORATORIES, LLC, MERZ GMBH & CO. KGAA, MERZ PHARMA GMBH & CO. KGAA and MERZ PHARMACEUTICALS GMBH Defendants.	Civil Action No. 15-cv-7488 CLASS ACTION JURY TRIAL DEMANDED

FIRST AMENDED CLASS ACTION COMPLAINT

I. Introduction

1. This is a civil antitrust action seeking treble damages arising out of the defendants' unlawful scheme to maintain a monopoly and to allocate the United States market for branded and generic versions of memantine hydrochloride (the "Memantine Hydrochloride Market" or "Market"). Namenda® ("Namenda") is a branded pharmaceutical product containing the active ingredient memantine hydrochloride. It is sold in the Market by Forest Laboratories, LLC ("Forest")[1] and used for the treatment of Alzheimer's disease. Sales of branded Namenda immediate release ("Namenda IR") and extended release ("Namenda XR") in the United States exceeded $1.75 billion per year prior to generic entry in July 2015, and the sales volume for memantine hydrochloride products stands to continue to grow consistent with the epidemiological projection that the number of Americans living with Alzheimer's will triple by 2050.

2. Forest has licensed the rights to market both Namenda IR and XR in the United States under U.S. Patent No. 5,061,703 (the "'703 Patent"), which is owned by Merz GmbH & Co. KGaA and/or Merz Pharma GmbH & Co. KGaA and/or Merz Pharmaceuticals GmbH ("Merz"). Forest and Merz claim that the '703 Patent covers the use of memantine hydrochloride to treat Alzheimer's disease. Forest's Namenda IR tablet products were approved by the Federal Food and Drug Administration ("FDA") in October 2003 and launched in the U.S. market in January 2004. Although the '703 Patent expired on April 11, 2015, Forest was granted pediatric exclusivity by the FDA in June 2014, extending the period of marketing exclusivity protection for Namenda to October 11, 2015. However, that regulatory exclusivity was

[1] Forest was acquired by, and became a wholly-owned subsidiary of, Actavis, plc on July 1, 2014; Actavis, plc began operating under the name Allergan, plc on or about June 15, 2015. Unless the context indicates otherwise, all references to "Forest" include successors in interest Actavis plc and Allergan PLC.

applicable only against generic manufacturers who did not submit Paragraph IV ("PIV") certifications challenging the '703 Patent with their memantine hydrochloride Abbreviated New Drug Applications ("ANDAs").[2] Despite the existence of numerous ANDAs with PIV certifications asserted and maintained as to the '703 Patent, no less-expensive generic versions of Namenda entered the market until July 11, 2015, three months ***after*** the '703 Patent expired, due to the anticompetitive behavior alleged herein.

3. Generic versions of brand name drugs contain the same active ingredient as their brand name counterparts, and also typically come in the same milligram strength(s), form (*e.g.*, tablet or capsule), and use the same route of administration as the branded version. Generics meeting these requirements, in addition to demonstrating bioequivalence – *i.e.*, demonstrating that the active ingredient of both the generic and brand are contained in the bloodstream of humans in the same relative amounts and periods of time – are clinically identical in that they give rise to the same positive clinical outcome and are deemed by FDA to be "AB-rated" to the branded counterpart drug. An "AB" rating in technical regulatory terms means the FDA has determined that the generic drug is "pharmaceutically and therapeutically equivalent" to its branded counterpart, the "Reference Listed Drug," and thus automatically substitutable for the brand drug at the pharmacy.[3]

4. The only material difference between generics and brand name drugs is their price – generics are typically at least 30% less expensive than their brand counterparts when there is a single generic competitor; this discount typically increases to 50-80% (or more) when there are multiple generic competitors on the market. As a result, generics constitute both (a) an

[2] For an explanation of the Hatch-Waxman regulatory scheme and the filing of a Paragraph IV ANDA by a company seeking to market a generic version of a brand name drug, s*ee* ¶¶ 32-41, *infra*.
[3] *See* Preface to the 34th Orange Book (2014) at xv, *available* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf.

opportunity for drug purchasers to obtain enormous cost savings; and (b) a serious threat to the monopoly power and profits of the manufacturer of the brand name drug facing generic competition. Indeed, AB-rated generics typically take 80% or more of the sales of a drug molecule from the brand name product within a year of generic entry. These extremely rapid generic erosion rates are due in large part to a unique feature of the pharmaceutical industry called drug substitution laws, which permit (and in many states require) dispensing pharmacies to substitute available AB-rated generic drugs for a brand drug unless the prescribing physician specifically orders otherwise.

5. Acutely aware of these realities, Forest engineered a scheme to improperly block generic competition for Namenda IR by: (1) brokering a conspiracy whereby certain generic manufacturers seeking to market AB-rated generic versions of Namenda IR in competition with Forest as soon as possible agreed and conspired with Forest and between and among each other to quit their legal challenges to the '703 Patent and delay launch until an identical date three months after the expiration of the '703 Patent in order to obtain competitive protection from each other through a "contingent launch" clause in their various settlement agreements with Forest;[4] then (2) using this improperly obtained period of additional exclusivity to launch the successor branded product, Namenda XR,[5] and force the conversion of the Memantine Hydrochloride Market from Namenda IR to the clinically equivalent (but not superior) Namenda XR. Forest's goal was to convert as much of the market as possible to Namenda XR prior to market entry of generic versions of Namenda IR because the generic versions of Namenda IR would not be AB-

[4] Contingent launch provisions provide that the generic manufacturer may enter the market on the earlier of: (a) the expiration of the agreed delay period, or (b) the date on which any other generic manufacturer launches a generic product. Thus, each generic manufacturer agrees to delay its market entry on the express condition that every other generic manufacturer does the same and for the same period of time.

[5] Namenda XR is the extended release version of Namenda. It possesses the same active ingredient and the same half-life as the original version of Namenda. *See* ¶¶ 160,187, *infra.*

rated to Namenda XR (since Namenda IR is a twice daily product and Namenda XR is once daily) and thus not automatically substitutable at the pharmacy. By implementing this scheme, Forest intentionally sought to destroy the normal market competitive forces that exist between a branded drug and AB-rated generic counterparts as intended by Congress via the Hatch-Waxman Act of 1984.

6. In early 2008, Forest and Merz began filing Hatch-Waxman patent infringement suits against multiple generic pharmaceutical companies, including Barr Pharmaceuticals, Inc. ("Barr"); Teva Pharmaceuticals USA, Inc.; Cobalt Laboratories, Inc. ("Cobalt"); Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid"); Lupin Pharmaceuticals, Inc. ("Lupin"); Upsher-Smith Laboratories, Inc. ("Upsher-Smith"); Wockhardt Limited ("Wockhardt"); Mylan Pharmaceuticals, Inc. ("Mylan"); Genpharm ULC and Genpharm, L.P. (jointly, "Genpharm,"); Interpharm Holdings, Inc. and Interpharm, Inc. (jointly, "Interpharm") (whose interests in the suit were soon to be acquired by a wholly owned subsidiary of Amneal Pharmaceuticals, LLC) ("Amneal"); Sun India Pharmaceuticals Industries, Ltd. ("Sun"); and Dr. Reddy's Laboratories Ltd. and/or Dr. Reddy's Laboratories, Inc. (jointly, "Dr. Reddy's") – each of which had filed ANDAs with the FDA to market AB-rated versions of Namenda IR prior to the expiration of the '703 Patent, and each of which claimed that the '703 patent was invalid and/or not infringed by the generic products they intended to launch. Under the Hatch-Waxman Act (discussed below), the mere filing of these lawsuits prevented the FDA from approving the generic drug applications for each of these generic manufacturers for 30 months, regardless of the merits of the lawsuits.

7. In 2009 and 2010, Forest and Merz settled their Hatch-Waxman lawsuits against all potential first-filing generic challengers, which included Barr, Teva Pharmaceuticals USA,

Inc., Cobalt, Amneal, Upsher-Smith, Wockhardt, Sun, Orchid, Dr. Reddy's, Lupin and Mylan (the "Potential First-Filing Generics"),[6] by entering into and brokering anticompetitive agreements (collectively, the "Contingent Entry Agreements") whereby each of the Potential First-Filing Generics: (1) agreed not to compete with Forest or enter the market prior to July 11, 2015, unless another generic competitor entered the market earlier (*e.g.* "contingent entry") ; and (2) received cash payments, the amounts of which have not been publicly disclosed. The July 11, 2015 entry date in each of the Contingent Entry Agreements was after the expiration of the '703 Patent and any other exclusivities that could prevent entry by any of the Potential First-Filing Generics.

8. Through unlawful "contingent launch" or escape clauses, which were substantively identical in all of the Contingent Entry Agreements, the Potential First-Filing Generics obtained protection from their fellow generic competitors by agreeing to delay the launch of their generic product from the date of settlement until exactly three months after the expiration of the '703 Patent *if and only if* all fellow generic companies did the same. By brokering the agreements, Forest and Merz ensured that without regard to the strength of the generic competitors' invalidity and non-infringement challenges to the '703 Patent, Namenda IR would have no generic competitors and Forest would maintain patent-generated monopoly profits until at least three months after the expiration of that patent.

9. Without the "contingent launch" provisions, each Potential First-Filing Generic, operating pursuant to its independent economic self-interest – as intended by the antitrust laws and Hatch-Waxman Act – realizing the significant number of competitors vying to be first to

[6] The generic company(s) that is first to file a substantially complete ANDA containing a "Paragraph IV" certification that a patent(s) applicable to the corresponding branded drug product is either invalid, unenforceable, or not infringed may be entitled to receive a period of 180-days during which no other ANDAs for the same branded drug may be approved. 21 U.S.C. § 355(j)(5)(B)(iv).

launch generic versions of Namenda IR and the particular value (described below) of being the first generic on the market, would have sought the earliest possible entry date – without regard to what its fellow Potential First-Filing Generics had agreed to – either by launching "at risk,"[7] litigating the patent suit to conclusion, negotiating its own earlier entry date in its settlement, or entering the market immediately upon expiration of the '703 Patent in April 2015. This competition among the Potential First-Filing Generics vying to be the first to market might well have made it difficult or perhaps impossible for Forest and Merz to get *all of the Potential First-Filing Generics* to settle or to agree to the same entry date: the first to settle would be worried that, whatever entry date it had agreed to, one or more of its fellow Potential First-Filing Generics would get a "better" deal, *i.e.*, an earlier entry date, in its own subsequent settlement with Forest and Merz, or would launch "at risk," would continue to litigate and win (and then launch), or would launch in April 2015 immediately upon expiration of the '703 Patent.

10. Indeed, absent the "contingent launch" provisions, each Potential First-Filing Generic, upon settling, would have the same worry in turn, and the last settling Potential First-Filing Generic would have every incentive to hold out for the earliest date of all. But, this is the very type of competition that is protected and promoted by the antitrust laws and the Hatch-Waxman Act. The "contingent launch" provisions, however, protected the Potential First-Filing Generics from each other – *i.e.*, dampened competition – by eliminating the risk that one of them would get an earlier generic entry date than any of the others. It did this by reducing the economic incentive each Potential First-Filing Generic otherwise would have had to seek an

[7] "At risk" entry refers to circumstances in which a generic has received final approval from the FDA to market its product but the infringement litigation is continuing and therefore the generic may be "at risk" of incurring infringement damages if it enters the market but loses the patent litigation.

entry date earlier than its fellow generic competitors by ensuring that any "earlier" entry would permit and trigger earlier entry by all.

11. The Contingent Entry Agreements were interdependent, and Forest and Merz induced the Potential First-Filing Generics to collude rather than compete by giving each the assurance and protection that if it agreed to delay competing until July 11, 2015, none of its generic competitors would come to market earlier.

12. During the period of delay that Forest secured from the Potential First-Filing Generics through the Contingent Entry Agreements, Forest implemented what its CEO referred to as a "forced switch" of the U.S. Memantine Hydrochloride Market from Namenda IR to Namenda XR, a product that offered no material benefit to patients,[8] but which has longer patent protection and is not AB-rated to generic versions of Namenda IR. Such a switch is detrimental rather than beneficial to the patient population (*i.e.*, those with moderate to late stage Alzheimer's disease) because their medical routines are set, they are extremely vulnerable, and conversion has and will keep prices of memantine hydrochloride artificially elevated for all purchasers (since prescriptions written for Namenda XR cannot be substituted with the therapeutically equivalent but less-expensive AB-rated generic versions of Namenda IR). In the simplest of terms, Forest and Merz brokered a deal that enabled each of the Potential First-Filing Generics to overcome the concern that it would not be in its economic interest to accept an entry date as late as July 2015, then used that generic launch delay period to convert the market to

[8] No studies have been done to show that Namenda XR is more effective than Namenda IR. As the Second Circuit recently observed: "Namenda IR and Namenda XR have the same active ingredient and the same therapeutic effect." *State of New York v. Actavis*, No. 14-4624, slip op at 16 (2d Cir. May 28, 2015). FDA concluded that "the efficacy, tolerability and safety profiles are expected to be similar. . . ." NDA No. 22-525, Clinical Pharmacology and Biopharmaceutics Review(s), at p.4 (available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022525s000_namenda_xr_toc.cfm).

Namenda XR, thereby indefinitely preserving its stream of monopoly profits from the Namenda franchise.

13. Forest carefully timed the launch of Namenda XR so as to avoid prematurely cannibalizing sales of Namenda IR, Forest's highest grossing product, yet still allowing sufficient time to force the memantine hydrochloride market to convert to Namenda XR prior to the launch of AB-rated generic versions of Namenda IR. Because the "forced switch" effectively removed Namenda IR from the market, as intended, and thereby significantly impeding automatic generic substitution at the pharmacy level (the most efficient means for generic pharmaceuticals to compete), when generics launched their generic version Namenda IR tablets in July 2015, generic manufacturers were able to capture a only small fraction of the Memantine Hydrochloride Market that they otherwise would have captured.

14. But for the anticompetitive Contingent Entry Agreements, many of the Potential First-Filing Generics would have launched their generic products earlier: (a) upon receiving FDA approval while the patent litigation was still pending (*i.e.*, "at-risk"); (b) upon prevailing against Forest in the underlying patent litigation; (c) via lawful, separate, and independent settlement agreements whereby reasonable parties in the position of the Defendants and the Potential First-Filing Generics would have provided for much earlier negotiated entry dates *without* the protection from competition that the contingent launch provisions provided; or (d) at the very latest in April 2015 after expiration of the '703 Patent. Similarly, but for the unlawful forced product switch from Namenda IR to Namenda XR, the Potential First-Filing Generics and other generics would have captured a much larger share of the Memantine Hydrochloride Market than they have been able to capture with the belated launch of their products beginning in July 2015. The smaller available market share may have additionally caused some would-be generic

challengers to abandon their efforts to market a generic version of Namenda IR altogether, thus compounding harm to competition. Plaintiff and members of the Class would have, in turn, substantially substituted the less-expensive generic versions of Namenda IR for their purchases of more-expensive brand Namenda IR, thus saving substantial sums of money.

15. Defendants' conduct was designed to and did in fact: (a) delay the entry of less expensive, AB-rated generic versions of Namenda IR; (b) fix, raise, maintain or stabilize the price of memantine hydrochloride; (c) allocate 100% of the United States market for memantine hydrochloride to Forest until three months after expiration of the patent; and (d) substantially foreclose the most effective means of generic competition in order to preserve a greater share of that market after the belated launch of generic Namenda IR in July 2015.

16. Forest's monopoly power in the Memantine Hydrochloride Market was maintained through willful exclusionary conduct, as distinguished from growth or development as a consequence of a legally-obtained valid patent, other legally-obtained market exclusivity, a superior product, business acumen, or historical accident.

17. As alleged below, defendants' scheme violated sections 1 and 2 of the Sherman Act, injuring plaintiff and the Class of direct purchasers it seeks to represent (as defined below) and causing them to pay overcharges.

II. Parties

18. Plaintiff J M SMITH CORPORATION, d/b/a SMITH DRUG COMPANY ("Smith Drug Company") is a corporation organized under the laws of the State of South Carolina and is located at 9098 Fairforest Road, Spartanburg, South Carolina 29301. During the class period, as defined below, Smith Drug Company purchased brand Namenda directly from Forest at supracompetitive prices and has thereby been injured.

19. Defendant Forest Laboratories, LLC is a Delaware corporation, with its principal place of business at 909 Third Avenue, New York, New York 10022. Forest is a company engaged in the development, marketing, and distribution of branded pharmaceutical products. On July 1, 2014, Forest was acquired by, and became a wholly-owned subsidiary of, Actavis, plc (now Allergan, plc).

20. Defendant Actavis, plc ("Actavis"), now known as Allergan plc, is incorporated under the laws of Ireland, with its principal place of business at 1 Grand Canal Square, Docklands Dublin 2, Ireland. Actavis also has a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054. Actavis markets a broad portfolio of branded and generic pharmaceuticals and has commercial operations in more than 60 countries around the world.

21. Defendant Merz GmbH & Co. KgaA is incorporated under the laws of Germany, with its principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany. Merz GmbH & Co. KgaA is a company engaged in the development, production, and distribution of branded pharmaceutical products.

22. Defendant Merz Pharma GmbH & Co. KgaA is incorporated under the laws of Germany, with its principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany.

23. Defendant Merz Pharmaceuticals GmbH is incorporated under the laws of Germany, with its principal place of business at Eckenheimer Landstrasse 100, D-60318 Frankfurt am Main, Germany.

24. Defendants Merz GmbH & Co. KgaA, Merz Pharma GmbH & Co. KgaA and Merz Pharmaceuticals GmbH are collectively referred to herein as "Merz."

25. All of defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by defendants' various officers, agents, employees, or other representatives while actively engaged in the management of defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, or with the actual, apparent, or ostensible authority of defendants.

III. Jurisdiction and Venue

26. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Smith Drug Company, and members of the Class (defined below) resulting from defendants' conspiracy and scheme to restrain trade in the United States market for memantine hydrochloride. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

27. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the class period, the defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this District.

28. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the United States, including in this District.

29. During the class period, Forest manufactured, sold and shipped Namenda in a continuous and uninterrupted flow of interstate commerce. The defendants' anticompetitive conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

30. During the class period, each defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their scheme.

31. This Court has personal jurisdiction over each defendant, because each defendant – throughout the United States and including in this District – has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal scheme and conspiracy. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. Regulatory Background

A. The Regulatory Structure for Approval and Substitution of Generic Drugs

32. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

33. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within thirty days of issuance any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

34. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the

manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. The Hatch-Waxman Amendments

35. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

36. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same relative extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355(j)(8)(B).

37. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less-expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

38. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[9] Generics are now dispensed 95% of the time when a generic form is available.[10]

2. ANDA Paragraph IV certification

39. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");

ii. that the patent for the brand drug has expired (a "Paragraph II certification");

[9] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), *available at* http://www.imshealth.com/cds/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf (last accessed June 6, 2014).
[10] *Id.* at 51.

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

40. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months from the date of receipt of the Paragraph IV notice, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (i.e., grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30 month stay.

3. First-filer's 180 day exclusivity period

41. Generics may be classified as (i) first-filer generics, (ii) later generic filers, and (iii) the brand's own authorized generic.

42. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180 day period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's

ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand product are either invalid or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first-filing generic has been on the market for 180 days, or until the first-filer exclusivity has been forfeited.

43. The Supreme Court has recognized that "this 180 day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first filer.[11]

44. A first-filer that informs FDA that it intends to wait until all Orange Book listed patents expire before marketing its product does not get a 180 day exclusivity period. Congress created this 180 day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

B. The Competitive Effects of AB-Rated Generic Competition

45. Generic versions of brand drugs contain the same active ingredient, and are determined by the FDA to be just as safe and effective as their brand counterparts. The only material difference between generic drugs and their corresponding brand versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. On average, generics are around 30% less expensive than their brand counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for all drug purchasers.

[11] *FTC v. Actavis, Inc.*, 570 U.S. 756, 133 S. Ct. 2223, 2229 (2013).

46. Since passage of the Hatch-Waxman Amendments, every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%.[12] As a result, competition from generic drugs is viewed by brand drug companies, such as Forest, as a grave threat to their bottom lines.

47. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

48. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Forest, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes (as here) resorting to illegal means.

[12] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (Jan. 2010) ("FTC Pay-for-Delay Study), *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (last accessed June 6, 2014).

1. As the Number of Generic Products on the Market Increases, Competition Increases, and Prices Decrease.

49. Once multiple generic competitors enter the market, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[13]

50. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift dramatically to generic sellers. A 2011 FTC Study found that generics captured 80% or more of sales in the first six months.[14] In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. This is so because, "[a]lthough generic drugs are chemically identical to their brand counterparts, they are typically sold at substantial discounts from the brand price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[15]

51. Once exclusivity is lost and generic entry occurs – an event sometimes referred to as the "patent cliff" – the brand manufacturer can expect a significant drop in profits, as it is forced to either compete by dramatically lowering prices, or accept dramatically lower sales. The tradeoff of longer exclusivity rights in return for quick and effective generic entry after loss of exclusivity was fundamental to the policies and procedures that Congress established in the

[13] *See, e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L. & ECON. (Oct. 2000); Tracy Regan, *Generic Entry and Price Competition in the Prescription Drug Market--18 Years after the Waxman-Hatch Act* (Univ. of Miami, Dep't of Econ., Working Paper, Feb. 14, 2004); R. Frank, *The Ongoing Regulation of Generic Drugs*, NEW ENG. J. MED., v. 357, pp. 1993-96 & n.20 (Nov. 2007).

[14] FTC 2011 AG Study, at 66-67.

[15] FDA WEBSITE, GENERIC DRUGS: QUESTIONS AND ANSWERS, *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm (last accessed June 6, 2014).

Hatch-Waxman Act, and embraced by the states in their generic substitution laws (explained below).

52. Nevertheless, confronted with an imminent loss of profits at the patent cliff, pharmaceutical companies often seek to stall the impact of generic competition. One method employed has been to enter into anticompetitive patent settlement agreements with multiple generic manufacturers that include "contingent launch" provisions, which provide assurance to the generic manufacturers that if they agree to delay launch until a widely-known, specific date, none of their generic competitors will come to market earlier.

53. A second strategy is a "product extension" strategy whereby the branded company facing a patent cliff develops a follow-on drug with a later patent expiration, and encourages patients and their physicians to switch from the drug going off patent to the new version of the drug. Because generic versions of the original drug will not be AB-rated to the new version of the drug, if physicians write prescriptions for the new version instead of the original version, then generic entry will be thwarted – even if, in practice, the cost savings offered by the generic drug far outweigh any advantages offered by the new version of the drug. Sometimes these follow-on drugs may be truly better than the original drug. In other instances, such as here, the new versions of the drug offer little to no therapeutic advantage over the prior versions, and the reformulation of the drug is merely an attempt to game the regulatory system and interfere with effective price competition between branded and generic drugs. Efforts to switch patients to a follow-on drug with little or no clinical benefit – solely for the purpose of interfering with generic competition and extending the monopoly life of a drug franchise – is sometimes referred to as "product hopping."

54. In this case, Forest utilized both strategies to thwart generic competition: it induced at least seven generic ANDA filers to delay launch until the same date – three months after the expiration of the '703 patent – with agreements containing substantively identical contingent launch provisions, then used the delay period that it had brokered to implement a forced product hop from Namenda IR to Namenda XR, which offered no clinical benefit to patients.[16]

C. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

55. An anticompetitive agreement entered into between the brand and first-filer generic often subjects later ANDA filers to the delayed entry date agreed to between the brand manufacturer and its conspiring first-filer generic.

56. In the absence of an anticompetitive agreement between the brand company and the first-filers, the later ANDA filers have pro-competitive incentives. They are motivated to expend resources to challenge the brand company's patent (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

57. When an anticompetitive agreement with the first-filer is already in place, however, litigation becomes less attractive to later filers. The later generic manufacturers know that the first-filer is not leading the charge against the brand's patent (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive, reverse payment settlement). The later generics have to bear the brunt of the litigation costs themselves, and, upon prevailing in the patent litigation, expect to face competition from at least the first-filer generics, and typically an authorized generic as well. The settlements between a brand and first-

[16] In fact, this switch was potentially detrimental to a patient population with a very fragile drug prescription schedule – evidenced by the fact that, despite strong marketing efforts by Forest, doctors were initially unwilling to switch their patients from Namenda IR to XR.

filer generics will often provide that, if a later generic filer launches its generic before the delayed date agreed to by the brand and the first-filer, the first-filer is permitted to launch then as well – greatly reducing the incentive the later filer would otherwise have to continue fighting to enter as soon as possible.

58. Thus, some later generics decide to simply give in to, or even join, the conspiracy between the brand company and the first-filer generic and drop their challenges to the brand's patents and stay off the market until after entry by the first-filer.

59. Such agreements are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking access to more affordable generic drugs, forcing purchasers to buy the expensive brands instead.

60. Here, the large number of potential first-filing generics created a situation where no single first-filing generic had expectations of the usual substantial revenues that first-filing generics typically enjoy during the exclusivity period and thereafter. As a result, each of the potential first-filer generics was incentivized to beat the competing first-filer generics to market in order to maximize revenues and recover the expenses associated with the preparation and prosecution of their ANDAs, as well as costs incurred in Hatch Waxman litigation with Forest and Merz. In this context, however, their interests would be better served by agreeing to delay launch in exchange for the elimination of any theoretical patent risk, but only if all other generics collectively did the same. Otherwise, each first-filer would face the potentially substantial economic detriment of being sidelined while other generics entered the market and exploited the lucrative first-filer advantage (explained below).

61. The anticompetitive Contingent Entry Agreements brokered by Forest and Merz, and continuously performed by all parties to those agreements from their date of execution to the present, have resulted in many years of unlawful monopolization in the market for Namenda and its AB-rated generic equivalents, including, as described below, the exclusion of generic competition for three months beyond the exclusionary scope of the '703 patent.

D. Brand Companies Have Strong Financial Incentives to Introduce New Versions of Products Solely to Protect Their Monopoly Profits by Impeding Generic Substitution.

71. The threat of AB-rated generic competition creates a powerful incentive for brand companies to protect their revenue streams. This incentive can prompt brand companies to create innovative new products or new versions of old products that offer real medical benefits to patients. It may also drive brand companies to seek to obstruct generic drug competition by making changes to existing products that offer patients little or, as here, no clinical advantages whatsoever, but are intended to interfere with the normal brand-to-generic competition contemplated and encouraged by the Hatch-Waxman Act and various state laws.

72. Product hopping tactics can be an effective, albeit anticompetitive, way to game the regulatory structure that governs the approval and sale of generic drugs, thereby frustrating the efforts of federal and state law designed to promote and facilitate price competition in pharmaceutical markets. As discussed in detail below, a brand company can interfere with the mechanism by which generic drugs compete by making non-therapeutic changes to its branded product, and can effectively prevent generic competition, not because the reformulated product is an improvement over the original version of the product or is preferred by consumers, but simply because it differs in strength, route of administration, or, as here, dosage form.

73. An AB-rating is particularly significant to a generic manufacturer because, under Hatch-Waxman and most state generic substation laws (commonly referred to as Drug Product

Selection laws ("DPS laws")), pharmacists may (and in many states, must) substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing physician (unless the prescription is denominated "Dispense as Written" or "DAW"). Indeed, both Congress and state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously (a) engaging in the type of heavy promotion or "detailing" typically done by brand-name manufacturers, and (b) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

74. DPS laws are a critical element in facilitating lower-cost generic competition. These laws permit effective price competition between branded and generic drugs at the pharmacy. If pharmacists need to contact the physician to ask permission to substitute a generic drug for the chemically-identified brand name drug each time the pharmacist filled a prescription, that would significantly and unnecessarily increase the costs and time required for dispensing generic drugs and impede the use of cheaper generic drugs.

75. The price competition at the pharmacy that DPS laws facilitate is the primary mechanism by which generic drugs are able to compete and reach the market. Competition at the pharmacy is especially important due to the unique characteristics of pharmaceutical markets. Generic manufacturers take market share away from branded pharmaceuticals by making their generic drugs available at a discount. They do not engage in expensive marketing to physicians and patients as branded drug companies do. Significant marketing expenditures by a generic manufacturer would likely increase the price of that generic and would not necessarily lead to greater sales by the marketer because generic entry commoditizes the market. Thus when there is more than one generic on the market, a generic manufacturer marketing its product to

physicians or patients has no way to guarantee that, once the physician is convinced to write a prescription for the generic drug in question, that pharmacist will dispense that manufacturer's product rather than one manufactured by another generic manufacturer.

76. Because it typically would not make economic sense for a generic manufacturer to market its drug to patients and doctors, the primary means by which generic manufacturers obtain sales is through price competition at the pharmacy, made possible through the application of DPS laws. Indeed, this is fundamental to the existing regulatory framework. For these reasons, among others, the Federal Trade Commission explained in a recent amicus brief that "[a]s a practical matter, if a generic cannot be substituted at the pharmacy counter, the economically meaningful market for the generic product disappears."[17]

77. AB-rated generic competition enables purchasers to (a) purchase generic versions of brand-name drugs at substantially lower prices, and/or (b) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic product, there is no bioequivalent generic drug which competes with the brand-name drug and therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably without losing all or a substantial portion of its brand-name sales.

78. This statutorily mandated process, however, can be anticompetitively manipulated when brand-name drug companies, like Forest here, introduce another version of an already-existing drug that is no safer and no more effective than the original version (the "new" version is typically a minor, non-therapeutic reformulation), and switch the market to the "new" version thereby causing the conversion of prescriptions for the original drug to be written for the "new"

[17] Brief for Federal Trade Commission as Amicus Curiae at 9, *Mylan Pharms., Inc. v. Warner Chilcott Pub. Co.*, No. 12-3824 (E.D.Pa. Nov. 21, 2012) [hereinafter "FTC Mylan Amicus Brief"], *available at* http://www.ftc.gov/sites/default/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.et-al.v.warner-chilcott-public-limited-company-et-al./121127doryxamicusbrief.pdf.

version. The result is that, by the time generic versions of the original brand-name drug reach the market, there are few, if any, prescriptions being written for the original brand version and, because there is some slight clinically insignificant difference between the generic drug and the "new" brand drug (*e.g.*, dosage form), state substitution laws will not allow the pharmacist to substitute the less-expensive generic for the more-expensive brand. Due to the barriers that prevent effective competition between generics and branded drugs at the pharmacy when state generic substitution laws do not act to facilitate substitution, the branded manufacturer will thus avoid the "patent cliff" that the Hatch-Waxman Act seeks to promote.

79. Successful implementation of a product hopping strategy typically requires that patients be switched prior to generic entry. Accomplishing the switch at this time ensures that the generics have no chance to compete for those patients via the more efficient mechanisms that the state substitution laws provide. As the FTC explained recently: "[i]f the brand manufacturer reformulates its product before a generic receives FDA approval," then the generic manufacturer is unlikely to be able to make significant sales with a generic version of the original branded drug.[18] Instead, "the generic's only practical option is to go back to the drawing board and reformulate its own product to be bioequivalent to the brand reformulation and thus substitutable at the pharmacy."[19] Of course, even that strategy will not work if the new formulation is patent protected or if the brand decides to implement yet another reformulation.[20]

[18] FTC Mylan Amicus Brief, p.10.
[19] *Id*.
[20] The barriers to entry by a generic drug manufacturer are high. Such companies must first formulate a non-infringing generic version of the brand name drug; conduct bioequivalence studies and other studies needed to support the ANDA; file the ANDA and work with FDA on any issues that arise regarding approval; either challenge relevant patents or wait for them to expire; wait for expiration of any applicable regulatory exclusivities; and invest in manufacturing facilities for the commercialization of the product. It is not economically rational for generic manufacturers to engage in these costly activities until regulatory and patent exclusivity expirations near. This is all the more so when generic companies have already heavily invested in formulating and pursuing FDA approval of a generic version of a brand name drug only to have the brand name manufacturer make a therapeutically meaningless

80. Importantly, once a brand manufacturer has successfully achieved a switch to a follow-on product, it can expect that most "switched" patients will not make a second switch back to the generic version of the original product (when the generic is released). There are several reasons why this is the case, all generally relating to the ineffectiveness and inefficiency of price competition by generics in the absence of the application of generic substitution laws. First, as explained above, it would not make business sense for generic manufacturers to engage in marketing efforts to encourage physicians and patients to switch patients' prescriptions back to a generic version of the original drug – and doing so would undermine the feasibility of selling low cost generic drugs.

81. Second, absent a specific request from a patient, physicians are unlikely to act on their own to switch the patient back. As explained by the FTC: "The physician – who selects the drug product but does not pay for it – has little incentive to consider price when deciding which drug to prescribe."[21]

82. Third, while patients are concerned about price, they are frequently unaware that comparable, lower-cost generic drugs are on the market (and as noted, it is unfeasible for generic manufacturers to market to them).

83. Finally, while insurers may be aware of competing generics and motivated to encourage switching, they face substantial challenges in doing so. Even when they engage in

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formulation change and switch the market to that new formulation for the anticompetitive purpose of thwarting meaningful competition from the existing generic product. This puts the generic manufacturer in the position of having to scrap its investment in the initial generic version of the drug and re-invest in developing a second generic product equivalent to the next version of the branded counterpart drug, all in the hopes that additional switches will not take place prior to approval and launch of the second generation generic product. *See, generally, Abbott Laboratories v. Teva Pharm. USA, Inc.*, 432 F.Supp.2d 408 (D. Del. 2006).

[21] *Id.* at p.6.

substantial efforts to encourage patients to switch, these efforts are frequently very costly, and may have limited success.

84. There are various tactics that a branded manufacturer may use to try to encourage physicians and patients to switch to its new follow-on drug prior to generic entry. Commonly, the company will aggressively promote the follow-on drug and stop marketing the original drug. The company will typically advocate to physicians that the new product is superior and should be prescribed instead of the original. At the extreme end of the spectrum, a pharmaceutical company may seek to *force* physicians and patients to make the switch to the new drug. This might be accomplished by announcing that the original product will be discontinued on a specified future date, restricting the distribution and availability of the original drug, or completely removing the original product from the market and leaving patients with no other option but to switch.

85. For a drug manufacturer seeking to implement a product extension strategy by *compelling* patients to switch drugs, it is especially important that the branded drug manufacturer take action before a generic enters the market. Prior to generic entry, the branded manufacturer controls all drug sales for the original drug and can use the tactics described above effectively to move patients from one of its own drugs to another. But after generic entry, there will be effective price competition between the original branded drug and generic substitutes as a result of the application of generic substitution laws, and most of the patients taking the original drug will likely switch to the generic version. Once that happens, the brand manufacturer still has the opportunity to compete on the merits, that is, to market to patients and physicians to convince them that the new, reformulated drug is worth the extra cost as compared to the generic. But the

opportunities available to the brand manufacturer to manipulate prescribing practices become much more limited.

86. As described below, in the case of Namenda, Forest implemented a product hop scheme designed to force physicians and patients to switch from the original version of Namenda to Namenda XR. In most cases, drug companies try to engineer a "soft switch" to the new version of the drug by heavily marketing it and arguing their best case as to its clinical superiority – without creating artificial barriers to the use of the original drug. In this case, however, Forest was not satisfied with that strategy because not many patients switched voluntarily, as doctors were hesitant to disrupt the delicate medication-taking routines of Alzheimer's patients without a medical reason. So, instead, in order to perpetuate its monopoly profits for several more years, Forest chose to implement a "hard switch" to *force* patients to switch to Namenda XR, whether they wanted to or not.

87. Defendants began implementing the hard switch in February 2014 by, among other things, widely publicizing that the original version of Namenda would soon be discontinued, thus leaving patients and their physicians with no choice but to use Namenda XR instead. Forest also sought to have the Centers for Medicare and Medicaid Services remove Namenda IR from the reference list that health plans serving Medicare patients use to determine which drugs to approve for payment. Finally, Forest took steps to make Namenda IR significantly more difficult to obtain by signing an exclusive distribution contract in November 2014 for Namenda IR engaging Foundation Care, a mail-order-only pharmacy, to remove Namenda IR from all retail store shelves effective January 2015 (according to the agreement). The agreement also provides that patients seeking to purchase Namenda IR must, in addition to a prescription, provide a physician certification that it is medically necessary for them to take

Namenda IR specifically, instead of XR. Forest projected that the transaction costs of obtaining Namenda IR through this method would ensure that less than 3% of current IR users obtained IR through Foundation Care.

88. Forest's forced switch was an effort to game the regulatory system and manipulate patients and physicians through business practices that had no real business purpose other than to impede competition from cheaper generic drugs and perpetuate Forest's monopoly profits. A physician recently aptly described Forest's conduct in a complaint to the company as immoral and unethical.[22] It also constitutes unlawful monopolization and an unreasonable restraint of trade in violation of state and federal antitrust laws.

89. After a product hop, generic manufacturers with AB-rated generic version of the old brand formulation have very limited options for marketing their product, all of which result in significantly higher prices for purchasers: (a) implement their own extensive sales and marketing campaign for their generic drug, which dramatically increases the price for the product (and, as a practical matter, acts as a barrier to meaningful market entry); (b) abandon altogether their generic product, meaning no generics are available; or (c) enter as a normal generic in a greatly and artificially diminished segment of the market resulting in dramatically lower sales and savings to purchasers.

V. Statement of Facts

A. Alzheimer's Disease and Namenda.

90. Memantine hydrochloride, branded and marketed by Forest as Namenda in the United States, is an N-methyl-D-aspartate ("NMDA") receptor antagonist. Essentially, Namenda

[22] In addition, the media recently quoted an Alzheimer's patient describing Forest's tactic in this way: "They are yanking the rug right out from under me…And that is not fair play." *See* Jonathan Lapook, *Forced Switch? Drug Cos. Develop maneuvers to hinder generic competition*, CBS News, Aug. 28, 2014, http://www.cbsnews.com/news/drug-companies-develop-maneuvers-to-hinder-generic-competition/.

works to prevent the overstimulation by glutamate, an amino acid that excites nerves, and in excess, is a powerful nerve-cell killer. Namenda is the only NMDA antagonist approved by the FDA for treatment of Alzheimer's in the United States, and has been approved for use in patients with moderate and severe Alzheimer's disease.

91. Alzheimer's disease is a progressive and irreversible disease of the brain that is the most common cause of dementia worldwide. It currently afflicts over five million Americans and is the sixth leading cause of death in the United States. As the population continues to live longer, the number of people living with Alzheimer's is expected to triple by 2050. Alzheimer's disease is a devastating neurodegenerative disorder. Patients with Alzheimer's progressively deteriorate, with worsening symptoms, until death. While the symptoms of Alzheimer's vary from patient to patient, common early symptoms include short-term memory loss, difficulty performing familiar tasks, disorientation, trouble with language, and mood swings. Patients with more severe Alzheimer's may be unable to walk or be unable to recognize and communicate with family members and friends. As the disease progresses, patients are unable to function independently, and become more and more dependent on caregivers.

92. Currently, there is no cure for Alzheimer's. Patients depend on medications approved to treat the disease, hoping that the medications may be able to temporarily alleviate some symptoms or slow down the progression of others.

93. Memantine had been marketed in Germany since the 1990s for the treatment of dementia, among other things. On or about June 2000, Merz, a German company, and Forest entered into a license and cooperation agreement for the development of memantine to be used for Alzheimer's. As part of the agreement, Forest obtained exclusive rights to market a memantine product in the United States under Merz's '703 Patent.

94. In December 2002, Forest submitted a New Drug Application ("NDA") to FDA, seeking approval to market memantine hydrochloride tablets (5mg and 10mg) – branded as Namenda – for the treatment of Alzheimer's.

95. The '703 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), which identifies and provides certain information regarding the patent covering Forest's memantine hydrochloride product (Namenda). The '703 Patent, obtained in 1991, originally had an expiration date of April 11, 2010.

96. Forest's New Drug Application ("NDA") No. 21-487 was approved in October 2003 for Namenda immediate release (IR) tablets.

97. In January 2004, Forest commercially launched Namenda IR tablets in the United States.

98. Namenda became a very successful drug for Forest, with revenues of over $1.75 billion in the twelve months ending in June 2014. Forest also sells an oral solution version of Namenda, which has less than 5% of Namenda's sales, and is not material here.

99. In the years leading up to 2010, Forest sought to extend the life of the '703 Patent as a means of extending its monopoly profits on Namenda. To do so, Forest submitted an application to the Patent and Trademark Office ("PTO") seeking a five-year patent extension, the maximum allowed under Hatch-Waxman, for the time spent obtaining FDA approval for Namenda IR tablets (during which time the patent "clock" was ticking but Forest could not market the drug). In March 2009, the PTO granted Forest the entire five-year extension. As a result, the '703 Patent was set to expire on April 11, 2015, rather than the original date of April 11, 2010.

100. In January 2014, Forest submitted an application to FDA seeking an additional six months of pediatric exclusivity for Namenda IR tablets, based on studies regarding the use of memantine in pediatric patients with autism.

101. On June 18, 2014, Forest announced that FDA had granted its request for six months of pediatric exclusivity for memantine. As a result, the earliest date that a generic manufacturer *who did not wish to challenge the '703 Patent* could come to market with an AB-rated equivalent of Namenda IR was October 11, 2015.

B. Forest Sues the Generics Triggering a Thirty-Month Hatch-Waxman Stay

102. Beginning in late 2007, numerous generic manufacturers filed ANDAs with FDA seeking to market AB-rated generic formulations of Namenda IR, contending via Paragraph IV certifications that the '703 Patent was invalid and/or not infringed by their products. Pursuant to certain provisions of the Hatch-Waxman Act, Forest filed patent infringement lawsuits against each company that filed an ANDA for Namenda.

103. In the twelve-week period beginning on October 16, 2007, at least twelve (12) generic manufacturers sent Paragraph IV certification notices to Forest indicating that each had submitted ANDAs seeking approval to manufacture, use, or sell generic immediate release memantine hydrochloride in the U.S. prior to the expiration of the '703 Patent (which they claimed was invalid, not infringed by their proposed products, or both): (1) Barr (now Teva) sent notice on October 16, 2007; (2) Teva sent notice on November 30, 2007; (3) Cobalt (now owned by Allergan) sent notice on December 6, 2007; (4) Orchid sent notice on December 11, 2007; (5) Lupin sent notice on December 14, 2007; (6) Upsher-Smith sent notice on December 14, 2007; (7) Wockhardt sent notice on December 15, 2007; (8) Genpharm sent notice on December 18, 2007; (9) Mylan sent notice on December 18, 2007; (10) Interpharm (now Amneal) sent notice

on December 19, 2007; (11) Sun sent notice on December 20, 2007; and (12) Dr. Reddy's sent notice on January 4, 2008.

104. In January 2008, Forest and Merz filed Hatch-Waxman lawsuits in the United States District Court for the District of Delaware against Barr, Cobalt, Lupin, Orchid, Teva, Upsher-Smith and Wockhardt alleging infringement of the '703 Patent. Merely by filing these suits (and regardless of their merit or lack thereof), Forest and Merz triggered automatic 30-month Hatch-Waxman stays, continuing through mid-2010, during which time the FDA could not approve any of the aforementioned generics' ANDAs for AB-rated equivalents to Namenda tablets. These lawsuits were consolidated in June 2008 under lead case No. 08-cv-00021 (D. Del).

105. Also in January 2008, Forest and Merz filed Hatch-Waxman lawsuits in the United States District Court for the District of Delaware against Dr. Reddy's, Genpharm, Interpharm (for whom Amneal was later substituted), Mylan, and Sun alleging infringement of the '703 Patent. Merely by filing these suits (and regardless of their merit or lack thereof), Forest and Merz triggered automatic 30-month Hatch-Waxman stays, continuing through mid-2010, during which time the FDA could not approve any of the aforementioned generics' ANDAs for AB-rated equivalents to Namenda tablets. These lawsuits were later consolidated under lead case no. 08-cv-00052 (D. Del.).

106. On information and belief, Barr, Teva Pharmaceuticals USA, Inc., Cobalt, Amneal, Upsher-Smith, Lupin, Mylan, Sun, Orchid, Dr. Reddy's, and Wockhardt (the Potential First-Filing Generics), were all first to file substantially complete ANDAs with Paragraph IV certifications to the '703 Patent. As a result, each would be entitled to 180-days of *shared* marketing exclusivity for generic Namenda, and any one of them could trigger the running of the

180-day exclusivity period by either launching a product or obtaining a judgment of invalidity or non-infringement of the '703 Patent.

C. Generics Get Tentative Approvals; Forest and the First-to-File Generics Enter Contingent Entry Agreements Prior to the Expiration of the Thirty-Month Stays; First-to-File Generics Agree to Delay Launch Beyond the Exclusionary Scope of the '703 Patent.

107. On information and belief, the 30-month stays barring the FDA from finally approving the first-to-file generics' ANDAs would begin to expire in or about April 2010 (the expiration dates vary slightly from generic to generic because the stay commences for each generic on the date of Forest's receipt of that generics' paragraph IV notice).

108. From 2007 to 2009, during the 30-month stay period, Forest and Merz litigated the patent infringement suits against the multitude of generic challengers in the United States District Court for the District of Delaware.

109. The generic defenses asserting that the claims of the '703 Patent were anticipated and obvious in view of the prior art and that Forest improperly sought and obtained a longer patent term extension than that to which it was entitled, among others, were strong. As such, litigation with any generic challenger through trial posed a significant risk of patent invalidation for Forest. In addition, one or more of the generic challengers advanced non-infringement defenses that posed additional risk to Forest.

110. Forest was aware that the '703 Patent was weak and that it would not be able to obtain injunctions to stop any of the first-filing generics from launching their generic versions of Namenda once they started receiving final FDA approval of their ANDAs from the FDA (which was imminent by mid-2010).

111. In order to protect and maintain its monopoly power in the Memantine Hydrochloride Market, Forest would have to induce all of the Potential First-Filing Generics to

refrain from selling their generic versions of Namenda, because the entry of even a single generic product would quickly cause the majority of memantine hydrochloride purchases to switch from Forest's branded Namenda to the substantially less-expensive, but bioequivalent, generic version(s) of Namenda.

112. The Potential First-Filing Generics were individually motivated to enter the market as quickly as possible. With the large and unprecedented number of potential first-filers, the Potential First-Filing Generics (at least some of whom had a history of prior at-risk launches) were particularly motivated to be the first to obtain FDA approval and launch in order to capitalize not only on being the exclusive generic on the market for an indefinite period, but also on the continuing benefits of having been first to establish supply relationships with large purchasers like major pharmacies and retail chains (*i.e.*, the "first-filer advantage"). Each of the Potential First-Filing Generics would have to receive something of immediate and substantial value (such as cash and/or protection from competition with each other) in order to induce them to forego their right to profit from the sale of their generic versions of immediate release Namenda tablets.

113. With trial scheduled in the Delaware patent litigation against the various generic defendants in 2010, Forest and Merz settled with the following generic companies on or about the following dates: July, 2009 – Cobalt Laboratories, Inc. and Teva Pharmaceuticals; September, 2009 – Upsher-Smith Labs, Wockhardt, Ltd., Amneal Pharmaceuticals, LLC, and Apotex Corp.; October, 2009 – Sun Pharmaceuticals; December 2009 – Lupin Pharmaceuticals and Dr. Reddy's Labs; April, 2010 – Orchid Chemicals & Pharmaceuticals; July, 2010 – Mylan Pharmaceuticals, and several other generic ANDA filers.

114. In connection with these settlements, Forest entered into licensing agreements with Teva (including Barr, which had become subsidiary of Teva), Amneal, Dr. Reddy's, Lupin, Sun, Upsher-Smith, Cobalt (later acquired by Watson Pharmaceuticals Inc., which was later acquired by Actavis, which is now operating as Allergan), Mylan, Orchid, and Wockhardt whereby Forest provided to each of them the assurance and protection that if it agreed to delay competing until January 11, 2015, none of its generic competitors would come to market earlier and enjoy first-filer sales while the settling generic remained on the sidelines. On information and belief, Forest additionally provided undisclosed amounts of cash to each settling generic. In exchange, the foregoing generic defendants agreed to discontinue their efforts to challenge the '703 Patent and all of them agreed to refrain from launching their generic products until the exact same day approximately five years later.

115. At the same time that these settlement agreements were consummated (or shortly thereafter), Forest and Merz settled their Hatch Waxman infringement suits against any and all other Potential First-Filing Generics. On information and belief, Forest provided each of these generics the same protections against competition from other the generics through "contingent launch" provisions as well as other valuable consideration. In exchange, each settling generic agreed to discontinue their efforts to challenge the '703 Patent and refrain from launching their generic products until the exact same day provided in Forest's settlement agreements with all other generic manufacturers.

116. On information and belief, each of the Contingent Entry Agreements contains a provision extending the agreed generic launch date from January 11, 2015 to July 11, 2015 in the event that, subsequent to the consummation of the agreements, Forest was granted an additional six-month pediatric exclusivity period.

117. As is apparent from the fact that the Contingent Entry Agreements provide for identical generic entry dates, the agreements were either negotiated with the simultaneous participation of multiple Potential First-Filing Generics or were negotiated under circumstances where settling Potential First-Filing Generics were informed of the negotiated entry dates of other Potential First-Filing Generics. In fact, some of the settlements with certain Potential First-Filing Generics were signed on the same days in July 2009, September 2009, and July 2010.

118. In total, Forest settled approximately a dozen patent infringement lawsuits with generic challengers in the one-year period leading up to the anticipated expiration of the 30-month stays in mid-2010.[23] By that time, all patent challenges brought by potential first-filing generic manufacturers seeking to market generic versions of immediate release Namenda tablets before the expiration of the '703 Patent were settled and dismissed. As expected, on or about July 11, 2015, several generic challengers launched their versions of immediate release Namenda tablets onto the U.S. market.[24]

119. Neither the defendants nor the Potential First-Filing Generics have publicly disclosed the amount of the cash payments (or other valuable consideration) given by Forest and Merz to the Potential First-Filing Generics pursuant to the Contingent Entry Agreements. On information and belief, the value of Forest and Merz's aggregate payments to all of Potential First-Filing Generics pursuant to the Contingent Entry Agreements total many millions of dollars.

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[23] *See* Forest's September 2009 Form 10Q filed with the United States Securities and Exchange Commission, pp. 15-16, available at http://www.sec.gov/Archives/edgar/data/38074/000003807409000048/forest10qsep09.htm; Forest press release dated July 22, 2010, available at http://investor.frx.com/press-release/corporate-news/forest-laboratories-inc-and-merz-pharma-gmbh-co-kgaa-settle-namenda-pat.

[24] Prior to the end of July 2015, Amneal, Dr. Reddy's, Lupin, and Mylan had all launched their generic versions of Namenda IR. In addition, defendant Allergan (formerly Actavis), successor in interest to Forest, had launched an authorized generic. With so many generics on the market, the price of generic Namenda IR quickly plummeted to less than 10% of the July 2015 Namenda IR brand wholesale acquisition cost ("WAC") price.

120. On information and belief, every Contingent Entry Agreement contained an identical, or nearly identical, contingent launch provision. That is, each agreement provided that the given generic manufacturer may enter the market on the earlier of: (a) the expiration of the agreed delay period, or (b) the date on which any other generic manufacturer launches a generic product.

121. The Contingent Entry Agreements were interdependent and anticompetitive in that each Potential First-Filing Generic would not have agreed to a July 11, 2015 entry date without the assurance that a generic competitor could not come to market earlier. None of the Potential First-Filing Generics would have agreed to delay entry for as long as they did (if at all) without similar agreements from all of their would-be generic competitors because: (1) they were all motivated to enter the market as soon as possible, and (2) they were motivated to avoid the economic detriment of being "stuck on the sidelines" while competing generics marketed their products. Thus the contingent launch provisions were the mechanism to facilitate a coordinated or collusive agreement – the means by which individual market delay concessions were knit together in a network of related, horizontal agreements among direct competitors. With that key provision in all of the Contingent Entry Agreements, the Potential First-Filing Generics understood and were assured that each of them shared the same set of risks and rewards.

122. In addition to being anticompetitive because they facilitated and/or coordinated collusive conduct between the Potential First-Filing Generics, the Contingent Entry Agreements were independently unlawful and anticompetitive because the six-month extension of the agreed launch date from January 11, 2015 to July 11, 2015 extended the agreements not to compete beyond the expiration of the '703 patent on April 11, 2015.

123. An award of pediatric marketing exclusivity by FDA does not extend or alter the expiration date of any patent:

> A pediatric exclusivity period is granted by the FDA to NDA holders under 21 U.S.C. § 355a. In contrast, a patent term extension is granted by the PTO to patent owners. A pediatric exclusivity period is granted because the NDA holder performs and reports on tests that the FDA requests it to do. It provides that, for six months after the patent on the drug expires, it will not permit anyone else, subject to certain exceptions, to market the finished drug product described in the NDA…During the instant pediatric exclusivity period, others were free to make, sell, offer to sell, import and use the compounds claimed in the [patent at issue]. Pediatric exclusivity is a regulatory privilege; a patent term extension is a patent privilege.

Altana Pharma AG v. Teva Pharms. USA, Inc., 2012 U.S. Dist. LEXIS 79166, 8-9 (D.N.J. June 7, 2012).

124. "Pediatric exclusivity attaching to the end of a patent term is not a patent term extension under 35 U.S.C. 156. Rather, it extends the period during which the approval of an abbreviated new drug application (ANDA) . . . may not be made effective by FDA." Guidance for Industry: Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food. Drug and Cosmetic Act, U.S.F.DA. (Revised, September 1999).

125. Under FDA regulations, pediatric exclusivity, if and when it is granted, applies only on an ANDA-by-ANDA basis. It does not attach to the end of a patent for an ANDA filer who maintains a Paragraph IV certification to the patent (unless the patent is found valid, enforceable, and/or infringed by that ANDA filer's proposed products). 21 U.S.C. § 355a(c)(1)(B)(ii).

126. The Supreme Court held in *Brulotte v. Thys Co.*, 379 U.S. 29 (U.S. 1964) that:

> [A]ny attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws.

Id. at 31 (quoting *Scott Paper Co. v. Marcalus Co.*, 326 U.S. 249, 256 (1945)).

127. Earlier this year, the Supreme Court reaffirmed *Brulotte* and its progeny, holding that an agreement not to compete based upon an expired patent "would impermissibly undermine the patent laws":

> Allowing even a single company to restrict its use of an expired or invalid patent, we explained, would deprive the consuming public of the advantage to be derived from free exploitation of the discovery. And to permit such a result, whether or not authorized by express contract, would impermissibly undermine the patent laws.

Kimble v. Marvel Entm't, LLC, 192 L. Ed. 2d 463, 469 (U.S. 2015) (internal quotations and citations omitted).

128. Accordingly, it is black letter patent law that a patentee's attempt to restrict the use of the invention beyond the expiration of the patent would be unenforceable and unlawful *per se*.

129. Here, on information and belief, all of the Potential First-Filing Generics maintained Paragraph IV certifications to the '703 Patent despite the settlement of the patent lawsuits with Forest. As a result, for all of those Potential First-Filing Generics, pediatric exclusivity did not attach to the '703 Patent and, to the extent the Contingent Entry Agreements prevented competition by the Potential First-Filing Generics' after April 11, 2015, they were independently unlawful.

130. Had the Potential First-Filing Generics launched generic versions of Namenda IR upon receiving FDA final approval in 2010, or at the conclusion of the trials for patent infringement (as several of them were preparing and poised to do prior to the Contingent Entry Agreements), or at the termination of Forest's patent rights on April 11, 2015, the generics would have rapidly driven down the price of memantine hydrochloride, creating a commoditized market with little or nothing to distinguish one generic from another except price (as happened in

the weeks following generic launch in July 2015). Price competition between generics is responsible for much of the dramatic price drop that accompanies generic entry.

131. Absent Forest and Merz's unlawful contingent launch provisions under the Contingent Entry Agreements, Forest and each of the Potential First-Filing Generics would have settled in a manner less restrictive of competition, resulting in much less delay of generic entry than has happened with the contingent launch provisions in place. Absent the anticompetitive settlement agreements, generic competition would have commenced sooner because one or more of the following events would have occurred: (1) the generics would have prevailed in the patent litigation; (2) the Potential First-Filing Generics would have launched "at risk" prior to the resolution of the patent litigation; (3) Forest would have settled the litigation legally with an earlier generic entry date; or (4) the Potential First-Filing Generics would have launched immediately upon expiration of the '703 Patent in April 2015.

132. In January 2010, the FDA tentatively approved several generic ANDAs including those of Orchid, Lupin, Wockhardt, and Amneal (formerly Interpharm), meaning that these ANDAs were otherwise ready for approval, but could not receive final approval until the expiration of the 30 month stay. Thereafter, Teva received tentative approval in March 2010, followed by Mylan and Sun and Upsher-Smith in April 2010.

133. Potential First-Filing Generics received final FDA approval on the following dates: Dr. Reddy's on April 14, 2010; Sun on May 5, 2010; Teva on October 25, 2011; Orchid on March 12, 2012; Amneal on April 10, 2015; and Lupin on April 10, 2015. Mylan received tentative approval of its ANDA on April 2, 2010, with final approval following on January 30, 2015. Upsher-Smith received tentative approval of its ANDA on April 15, 2010, with final

approval following on July 31, 2015. But, because of the Contingent Entry Agreements, no generic launched until on or after July 11, 2015.

D. Effects of the Contingent Entry Agreements.

134. The Contingent Entry Agreements enabled each Potential First-Filing Defendant to overcome the concern that it would not be in its independent economic interest to accept an entry date as late as 2015.

135. The Contingent Entry Agreements enabled Forest to (a) delay entry of less expensive generic versions of Namenda 5 and 10 mg strengths in the United States, (b) fix, raise, maintain or stabilize the price of Namenda and its generic equivalents, (c) maintain a monopoly in the United States market for Namenda and its generic equivalents, and (d) allocate the market for Namenda and its generic equivalents exclusively to Forest through July 11, 2015.

136. The Contingent Entry Agreements had the effect of delaying competition for memantine hydrochloride for as many as five to six years. But for these agreements, the Potential First-Filing Generics would have begun marketing and selling their generic upon the receipt of final approval (or on an earlier date as provided for in settlement agreements without anticompetitive provisions).

137. Instead, as a result of the Contingent Entry Agreements, no generic launched a generic equivalent of Namenda IR tablets prior to July 11, 2015.

138. In addition, Forest and the Potential First-Filing Generics, knew and intended that their Contingent Entry Agreements would prevent other, later-filing generic companies from launching their own generic products.

139. The Potential First-Filing Generics represented all of the generics who would be entitled to market their generic versions of Namenda tablets for 180 days free from competition from other generic Namenda tablets (other than an Authorized Generic ("AG"), which is a

generic product licensed by Forest to be sold under its brand NDA). The operation of the Contingent Entry Agreements blocked any non-AG generic Namenda tablets from coming to market until 180 days after the launch by one of the first-filing generics because the FDA will not approve subsequently-filed ANDAs until the first-filers' exclusivity period has run.

140. In other words, the Contingent Entry Agreements served as a "cork in the bottle." So long as there was not a ruling invalidating the '703 patent or holding it not infringed (which would trigger the running of the first-filers' 180 day exclusivity period), the delayed launch of the first-filers' generic products called for under the Contingent Entry Agreements prevented any generic other than the Potential First-Filing Generics from entering the marketing until 180 days after July 2015.

141. Thus, defendants' Contingent Entry Agreements have delayed or prevented the sale of generic Namenda IR tablets in the United States for years, and unlawfully enabled Forest to sell Namenda tablets at artificially inflated, supracompetitive prices.

142. As described below, Forest intentionally structured the Contingent Entry Agreements in a manner that would guarantee to Forest the time necessary to: (1) obtain FDA approval of the new once-daily "Namenda XR" product, and (2) convert the Memantine Hydrochloride Market from Namenda IR to Namenda XR.

E. Forest Used the Delay that It Bought with the Anticompetitive Contingent Entry Agreements to Improperly Switch the Market from Namenda IR to Namenda XR, Greatly Reducing the Sales Available to Generic Equivalents of Immediate Release Namenda When they Eventually and Belatedly Enter the Market

143. With generic entry delayed for a significant period of time as a result of the settlements, Forest transitioned to the next phase of its scheme to extend its monopoly profits on Namenda and minimize the effects of the upcoming patent cliff: the "product extension" strategy. To successfully retain substantial sales for its Namenda franchise after generic entry,

Forest realized that it would have to accomplish two objectives: (1) introduce (or identify) a follow-on product with a later patent expiration, and (2) successfully switch a large number of patients to the new product. And, for the reasons explained previously (and further detailed below), Forest also realized that it would need to achieve these goals before the generic form of Namenda IR became available in the market.

144. Forest developed two new follow-on drugs with patent expiration dates significantly later than that of Namenda IR. First, it reformulated Namenda as an extended-release capsule (Namenda XR) to be taken once a day instead of twice daily. Second, it worked to develop a fixed-dose-combination product that would include both memantine and donepezil (the most commonly used acetylcholinesterase inhibitor, commonly abbreviated AChEI). The patents claimed to cover Namenda XR expire in 2029, while the '703 Patent (claimed to cover Namenda IR) expires in 2015. The patents that cover the new fixed dose combination expire even later than the Namenda XR patents.

1. Forest Launched Namenda XR in June 2013 and Sought to Convert Patients from Namenda IR to Namenda XR.

145. On August 21, 2009, less than a month after it had announced the first wave of settlements with generics challenging the Namenda IR patent, Forest submitted an NDA seeking to market Namenda XR, a once-daily, extended-release reformulation of Namenda. In support of its NDA, Forest submitted various studies supporting its claims of safety and efficacy for Namenda IR. In its NDA submission, Forest did not submit any head-to-head studies comparing the efficacy of Namenda XR to Namenda IR, nor did it otherwise demonstrate that Namenda XR was more efficacious than Namenda IR.

146. On or about June 21, 2010, the FDA approved Forest's NDA for Namenda XR, but Forest chose not to immediately launch the supposedly improved formulation.

147. Acknowledging the status of the Hatch Waxman infringement suits against the Namenda IR generic challengers as a factor in the launch timing of Namenda XR, Forest's Chief Operating Officer Larry Olanoff, explained: "We haven't said anything yet on that timing of launch; we're really taking it into consideration the marketplace, the impact of finalizing our own litigation activities around the immediate-release formulations as well as patents that are pending for the modified-release formulation."[25] While Forest initially emphasized that it was waiting for the PTO to act on certain patent issues related to Namenda XR,[26] it stalled the launch over a year-and-a-half after those issues were resolved.[27]

148. With Namenda sales lagging in the fall of 2012, Forest continued to sit on the allegedly improved Namenda XR product despite having been ready and able to launch the product for years. Indeed, Forest seemed to not even consider expediting the Namenda XR launch:

> In long term care, however, sales are below expectations…[W]e are currently taking steps to shore up Namenda in long-term care. This includes additional educational programs to physicians, nurse practitioners and consultant pharmacists who care for Alzheimer's disease patients in nursing homes. And we continue to remain confident about the Alzheimer's market and the Namenda revenue stream over the next several years. We expect Namenda to continue to be an important product for us. The mid-calendar 2013 launch of Namenda XR, a product that has a higher dose, a once-a-day formulation…should propel future growth for the Namenda franchise.

Forest Chief Commercial Officer Elaine Hochberg, Forest Laboratories F2Q13 Earnings Call Transcript, October 12, 2012, pp. 3-4.

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[25] *See* Forest Laboratories F1Q11 Earnings Call Transcript, July 20, 2010, p.9.

[26] According to Forest Chief Financial Officer, Francis Perrier, "[T]he XR strategy has been simmering in the background for some time now. Again, we're really waiting for the patent office to issue its complete published patent, which we hope will come soon." *See* Forest Laboratories F1Q12 Earnings Call Transcript, July 19, 2011, p.10.

[27] On October 18, 2011, Forest CFO Francis Perrier announced that Forest "received notification today that the USPTO has issued a second method of treating Alzheimer's disease patent for Namenda XR…we currently anticipate launching Namenda XR in later 2012 or early 2013." *See* Forest Laboratories F2Q12 Earnings Call Transcript, October 18, 2011, p.2.

149. Forest ultimately launched Namenda XR in June 2013, three years after obtaining FDA approval for the drug. The reason for the delay was to reap as much profit as possible from Namenda IR prior to launching XR and cannibalizing the blockbuster Namenda IR product. At the time Namenda XR was launched, Forest anticipated that generics would enter in January 2015. The June 2013 launch would give Forest sufficient time – 18 months – before generic entry to persuade health plans to put Namenda XR on a preferred tier and start moving patients to Namenda XR. With equivalent health plan coverage for XR and IR, patients would be more likely to switch from Namenda IR to Namenda XR prior to generic entry. Switching patients to Namenda XR prior to the launch of generic memantine hydrochloride became the key to Forest's profit strategy for Namenda.

150. Crucially, Forest realized that, to be successful, its product switch had to be accomplished before cheaper generic versions of Namenda IR ("generic Namenda" or "generic memantine") tablets became available in the market. This is because when generic memantine becomes available, there will be effective price competition between generic memantine and Namenda IR at the pharmacy, and as a result, many patients that remain on Namenda IR tablets after generic entry will likely switch to generic memantine. Forest knew that convincing these patients (or their physicians or health insurers) to switch to Namenda XR based solely on the merits of the different drugs would be very difficult. Forest would need to convince them to leave an inexpensive generic drug and pay significantly more (possibly five times more) for a different version of the very same drug (with no greater evidence of safety or efficacy) — solely because it could be taken once a day instead of twice daily.

151. However, if Forest could manage to persuade patients, physicians, and insurers to switch to Namenda XR prior to generic entry, then Forest would be able to prevent

manufacturers of generic memantine from engaging in effective price competition for these patients. This is because generic memantine tablets will not be AB-rated to Namenda XR, and therefore a pharmacist will not be able to substitute lower-priced generic memantine for Namenda XR under state substitution laws. Rather, the pharmacist would have to obtain physician consent for the substitution, which is time consuming and costly. Similar limitations would also be faced by a health insurer or generic competitor that sought to convince a patient to switch back to Namenda IR. By ensuring that generic manufacturers could not engage in meaningful competition for the sales to the switched patients, Forest's strategy made it much more likely that Forest would be able to retain these sales once generic memantine became available.

152. Consequently, Forest knew that switching a large portion of the Namenda patient base to Namenda XR prior to entry of generic memantine tablets would — by preventing the application of generic substitution laws and thus inhibiting effective price competition — create significant practical barriers to generic competition that would allow Forest to retain a significantly higher portion of its Namenda franchise sales in the face of generic substitution than it would have otherwise.

153. With the launch of Namenda XR in 2013, Forest stopped actively marketing Namenda IR and commenced an aggressive marketing campaign aimed at converting as many Namenda IR patients to XR as possible prior to the launch of generic versions of Namenda IR in July 2015.

154. In connection with the launch of Namenda XR in June 2013, Forest emphasized the importance of switching patients from Namenda IR to Namenda XR in internal documents,

sales training, and public statements. For example, an executive made a speech at a Namenda XR launch event:

> Our mission is to convert to Namenda XR and lift the franchise as a result of increased sales calls and combination therapy usage…Make no mistake about it, this is a sprint. We need to convert as much IR business to Namenda XR as quickly as possible.

Another executive wrote in a draft speech:

> [T]he core of our brand strategy with XR is to convert our existing IR business to Namenda XR as fast as we can and also gain new starts for Namenda XR. We need to transition volume to XR to protect our Namenda revenue from generic penetration in 2015 when we lose IR patent exclusivity.[28]

155. Also in June 2013, Forest's senior marketing executives considered two alternatives to the typical soft switch approach described above: completely discontinuing Namenda IR; or technically leaving the drug on the market, but severely restricting patient access with "limited distribution."[29]

156. In a presentation attached to a June 26, 2013 email between two of Forest's executives, the author notes that, with respect to Forest's conversion strategy, "[e]ither [a withdrawal or limited distribution] approach is unprecedented…[w]e would be operating in unchartered territory." The presentation also notes that "Prescribers, patients, caregivers may be confused or dissatisfied with either withdrawal or limited distribution scenario and may choose to discontinue Namenda treatment."[30]

157. Forest's pricing of Namenda XR confirms that its new formulation provided no material benefits over Namenda IR. Throughout the two-year period that Namenda XR was on

[28] *See* Redacted Opinion dated December 11, 2014 ("NYAG Opinion"), *State of New York v. Actavis, et al.*, No. 1:14-07473 (S.D.N.Y.), ECF No. 80, at p.48 (Sweet, D.J.).
[29] NYAG Opinion at p. 48.
[30] NYAG Opinion at p.49.

the market prior to generic launch in July 2011, Forest priced the new and supposedly-improved XR product at a 5% discount off of the Namenda IR WAC price, confirming that the new formulation provided no material benefits over Namenda IR. In addition, Forest agreed to pay rebates to health plans to make sure they put Namenda XR on the same tier as Namenda IR so that members would not have an incentive to choose Namenda IR and patients did not have to pay higher co-payments for Namenda XR. Had the reformulation actually increased the value to XR consumers as compared to IR consumers, Forest, as a rational profit-maximizing company, would have captured part of that value in its pricing. It did not attempt to capture any added value through increased pricing of the new XR formulation, but instead raised the price of the old IR formulation in relation to the new version and provided rebates on Namenda XR solely to convert the Memantine Hydrochloride Market from the original formulation to the new formulation.

2. Dissatisfied with the Results of its Efforts to Switch Patients and Physicians Voluntarily to Namenda XR, Forest Hatched a Scheme to Force Them to Switch.

158. As Forest sought to accomplish the switch from IR to XR, Forest executives had concerns that conventional strategies designed to influence patients' drug choices would be insufficient to convert a satisfactory number of patients from Namenda IR to Namenda XR prior to the entry of generic Namenda. Forest's internal projections estimated that only 30% of Namenda IR users would voluntarily switch prior to July 2015.[31]

159. There are several reasons why many patients and their physicians are reluctant to switch from Namenda IR to Namenda XR. First, the benefits of a switch from Namenda IR to Namenda XR are illusory. There are no studies showing that Namenda XR is more effective than

[31] *State of New York v. Actavis*, No. 14-4624, slip op at 19 (2d Cir. May 28, 2015).

Namenda IR; and the reduction in frequency of dosing that Namenda XR offers is a hollow benefit for most patients, particularly those who are already taking multiple medications.[32]

160. Second, Namenda XR has the exact same half-life (60 hours or more) as Namenda IR.[33] Prior to the launch of Namenda XR, physicians were aware that because of the lengthy half-life of Namenda IR, they could administer Namenda IR once-daily off-label in situations where reducing the patient's pill burden was desirable. The fact that Namenda XR's half-life is no greater than that of Namenda IR made it readily apparent to physicians that the new XR formulation provided no practical benefit over Namenda IR.

161. Third, for many, if not most, patients (and their physicians), the benefits of the change of administration are outweighed by the risks of changing the medical routine of a highly vulnerable patient. Given the potential risks to highly vulnerable later-phase Alzheimer's patients, without studies that show that a new medication has meaningful effects over a patient's current medication, physicians are frequently will not switch a patient from a medicine on which the patient is doing well to a new product.

162. Plainly, if the choice were left to physicians and patients, a large number of them would stay on the original formulation. As a result, despite the Forest's soft-switch tactics of aggressive marketing and pricing strategies, few physicians and their patients voluntarily converted from Namenda IR to Namenda XR.

163. With the conversion rate remaining at or below 20% several months after the Namenda XR launch, Forest ultimately became dissatisfied with the number of patients it would

[32] Most Alzheimer's patients are in long-term care facilities, where the average patient takes nine pills per day. Long term care facilities generally dispense pills three times a day. NYAG Opinion at pp.53-54.
[33] A medication's "half-life" is how long it takes for half of it to be eliminated from the bloodstream..

be able to switch through conventional strategies that relied on advocating for Namenda XR on its own merits.

164. Accordingly, Forest began to consider whether it should *force* physicians and patients to switch to Namenda XR whether they liked it or not. By at least as early as Fall 2012, Forest began to consider a plan to discontinue (or dramatically restrict distribution of) Namenda IR tablets several months prior to the availability of generic memantine, in order to accomplish through a "forced switch" what it was unable to accomplish based on promoting Namenda XR on its own merits and favorable Namenda XR pricing.

165. After a year evaluating whether to discontinue Namenda IR tablets prior to generic entry, by October 2013, Forest executives made the decision to discontinue Namenda IR.

166. According to its own predictions, the profits that Forest expected to make from the "forced switch" would come largely from impeding generic competition. As noted above, the typical effect of AB-rated generic entry is a 90% shift of brand market share to generics within one year. Forest's forced switch was expected to transition 80 to 100% of Namenda IR patients to XR prior to generic entry, and thereby impede generic competition.[34]

167. On October 18, 2013, a Forest executive emailed his colleagues, announcing the decision to withdraw Namenda IR from the market: "Dear all: Forest has made the decision to withdraw Namenda IR and transition all patients to Namenda XR." Forest CEO Brenton Saunders, testified that he made the decision, and by doing the hard switch, Forest hoped to hold on to a large share of its base instead of losing them to competition.[35]

168. During Forest's January 21, 2014 earnings call, Forest's CEO, Brenton Saunders, unabashedly explained the motivation behind the forced switch strategy: "[I]f we do the hard

[34] *State of New York v. Actavis*, No. 14-4624, slip op at 37 (2d Cir. May 28, 2015).
[35] NYAG Opinion at pp.49-50.

switch and we've converted patients and caregivers to once-a-day therapy versus twice a day, it's very difficult for the generics then to reverse-commute back, at least with the existing Rxs. They don't have the sales force, they don't have the capabilities to go do that. It doesn't mean that it can't happen, it just becomes very difficult. It is an obstacle that will allow us to, I think, again, go into a slow decline versus a complete cliff."[36] While Saunders discussed discontinuation of Namenda IR on numerous earning calls with investors, he never suggested that this business tactic would result in any cost savings or other efficiencies.

169. Similarly, another high level Forest executive, considering the likelihood that patients converted to Namenda XR would switch back to Namenda IR, observed that "anyone converted [to Namenda XR] is likely to stay converted."[37]

170. Forest knew that discontinuing or severely restricting the availability of Namenda IR would have serious consequences for patients. First, physicians' freedom to choose the medications they prefer for their patients would be eliminated, or dramatically curtailed. It would be Forest – rather than the patient or the physician – that would select the patients' therapy. By discontinuing or limiting distribution of Namenda IR tablets, Namenda XR would become the only readily available FDA-approved NMDA antagonist (aside from the rarely prescribed Namenda oral solution).

171. Second, patients would be forced to undergo an unnecessary change in medication and dosage that could be disruptive to their routine. It is very difficult to predict how this change in routine could impact a patient. In addition, the recommended dosage for Namenda XR (28 mg) is significantly greater than the typical dosage for Namenda IR (two 10 mg tablets, for a

[36] Forest CEO Brenton Saunders himself used the term "forced switch" in Forest's Q3 2014 Earnings Call (Jan. 21, 2014) ("We believe that by potentially doing a forced switch, we will hold on to a large share of our base users...").
[37] *See* Amended Complaint dated December 10, 2014, *State of New York v. Actavis, et al.*, No. 1:14-07473 (S.D.N.Y.), ECF No. 70, at p.28

total of 20 mg). These reasons are why many physicians were reluctant to move their patients to Namenda XR, and probably would not have done so if not forced by Forest.[38]

172. Forest also knew that widely publicizing the planned Namenda IR discontinuation would create an instant wave of conversion to Namenda XR because, among other reasons, physicians and payors would be compelled to act in advance of the actual discontinuation to ensure against any interruption in patient treatment.

173. Had Forest implemented the hard switch strategy, doctors and Alzheimer's patients could have decided whether the benefits of switching to once-daily Namenda XR outweighed the benefits of adhering to twice-daily therapy using less-expensive generic IR (or perhaps lower-priced Namenda IR). By announcing the removal of Namenda IR from the market prior to generic IR entry, Forest sought to deprive consumers of that choice. In this way, Forest avoided competing against lower-cost generics based on the merits of their redesigned drug by forcing Alzheimer's patients to take XR,[39] with the knowledge that transaction costs would make the reverse commute by patients from XR to generic IR highly unlikely.[40]

3. Forest Begins to Implement and then Modifies its "Forced Switch" Scheme.

174. On February 14, 2014, Forest began the "forced switch" by issuing a press release titled "Forest Laboratories to Discontinue Namenda® Tablets. Focus on Once-Daily Namenda XR®," and announced that it planned to discontinue the sale of Namenda IR tablets effective August 15, 2014. The press release further indicated that the Namenda XR formulation (and the rarely-prescribed oral solution) would still be available to consumers. On the same day, Forest notified the FDA that it would "be discontinuing the sale of Namenda [IR] Tablets effective

[38] In fact, Forest's own surveys indicate that many physicians, caregivers, and pharmacists are concerned about the potential harm to patients from the forced switch to Namenda XR.
[39] Alternatively patients could discontinue memantine-therapy entirely.
[40] *See State of New York v. Actavis,* No. 14-4624, slip op at 38 (2d Cir. May 28, 2015).

August 15, 2014." Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal.[41]

175. Forest also published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR tablets as of August 15, 2014, and urging caregivers to speak with their loved ones' "healthcare provider[s] as soon as possible to discuss switching to NAMENDA XR."

176. Forest's announcements of its plans for discontinuance were made to alert physicians and patients that Forest would be discontinuing IR so they could take appropriate action. Physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR.[42]

177. Forest hoped and expected that the February 14, 2014 public announcement and letters to physicians and caregivers would spur the "forced switch," but it also took other actions to ensure the success of its anticompetitive scheme.

178. For example, Forest also took steps to make it more difficult for Namenda IR tablets, or generic memantine, to be sold to Medicare patients — the largest customer base for the drug. A large portion of Namenda patients have their prescriptions paid for by Medicare, the government sponsored health insurance program that provides health insurance to most Americans over 65 years of age.

[41] *State of New York v. Actavis*, No. 14-4624, slip op at 21 (2d Cir. May 28, 2015). "Here, Defendants' hard switch – the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR – forced Alzheimer's patients who depend on memantine therapy to switch to XR (to which generic IR is not therapeutically equivalent) and would likely impede generic competition by precluding generic substitution through state drug substitution laws." *Id* at 36.

[42] NYAG Opinion, p.51.

179. In a letter dated February 18, 2014, Forest informed the Center for Medicare and Medicaid Services ("CMS"), the federal agency responsible for the Medicare program, that Forest was planning to discontinue Namenda IR tablets on August 15, 2014 and that CMS should remove Namenda IR tablets from the 2015 Formulary Reference File ("FRF"), which Forest knew would have the additional effect of discouraging health plans from including Namenda IR in their own formularies. As a result, health plans were more likely to discontinue covering Namenda IR tablets starting in January 2015, making it more difficult for physicians to prescribe Namenda IR.

4. Forest Repeatedly Exaggerated the Imminence of its Plans to Discontinue Namenda IR in Order to Maintain Constant Pressure on Physicians and Patients to Switch to Namenda XR.

180. Between February and June 2014, Forest regularly emphasized publicly its intent to discontinue Namenda IR on August 15, 2014.

181. In its Form 10-K filing with the Securities and Exchange Commission for fiscal year 2013 (ending March 31, 2014), Forest made multiple representations that it would discontinue Namenda IR on August 15, 2014. For example, in Item 7, which relates to "Management's Discussion and Analysis of Financial Condition and Results of Operations," Forest's 10-K reads: "In February 2014, the Company announced that it would discontinue the sale of Namenda tablets effective August 15, 2014."

182. In fact, however, high level executives at Forest were aware at the time that problems in the manufacturing and supply of Namenda XR presented a substantial risk that Forest would be unable to discontinue Namenda IR by August 15, 2014 because it would be unable to supply the market with sufficient amounts of Namenda XR to support the anticipated demand.

183. Instead of abandoning the anticompetitive product hop strategy altogether, Forest decided to announce a slight delay, but still maintain publicly that the discontinuation of Namenda IR was imminent so as to continue to exert coercive pressure on physicians and patients to switch to Namenda XR. Forest issued a statement on June 10, 2014 announcing that Forest would no longer be discontinuing Namenda IR on August 15, but would instead continue to market Namenda IR "into the Fall of 2014."

184. On November 5, 2014, in the Actavis 3rd Quarter Earnings Press Release, the company confirmed that it had regained the ability to fully supply the market with Namenda XR: "The Company continues to enhance manufacturing efficiencies related to its once-daily dosing of Namenda XR®, and is now producing product at capacities sufficient to support transitioning all Namenda IR twice daily tablet patients to its Namenda XR® once-daily product."

185. The announced discontinuation of Namenda IR had the intended effect of forcing a wave of conversion from Namenda IR to Namenda XR.[43] From January 2014 to May 2015, the conversion rate increased from 15% or less[44] to about 50% in anticipation of the lack of availability of Namenda IR.[45]

186. On December 15, 2014, Judge Sweet of the United States District Court for the Southern District of New York, finding a likelihood of success on similar antitrust product-hopping claims brought by the New York Attorney General, granted an injunction requiring Forest (and its parent company, Actavis (now Allergan)) to continue to make Namenda IR tablets available until thirty days after July 11, 2015. The injunction was affirmed by the Second

[43] There is no difference in coercive effect between complete discontinuation and the alternative limited distribution strategies that Forest has considered. The sole purpose of any such strategy would be to reduce antitrust scrutiny while accomplishing the exact same anticompetitive effects.
[44] Forest Laboratories 3Q14 Earnings Call Transcript, January 21, 2014, p.14.
[45] *See* NYAG Opinion, pp.85-86; *see also* Actavis Plc 1Q2015 Earnings Call Transcript, May 11, 2015, p.3. .

Circuit on May 22, 2015.[46] While the injunction may blunt the future effects of Forest's product hop strategy to some extent, the anticompetitive effects of the scheme have been substantially and irreversibly accomplished because, as Forest itself acknowledged above, "anyone converted [to Namenda XR] is likely to stay converted."

5. Effects of the Product Hop Scheme.

187. Namenda IR and Namenda XR have the same active ingredient. The one characteristic that Namenda XR possessed that made it significantly different from the previous version of Namenda – and which was crucial to Forest's anticompetitive scheme – was dosage form. Forest exploited this difference for one reason: it knew that generic Namenda IR would not and could not be considered "AB-rated" to branded Namenda XR, and thus pharmacists would not and could not legally substitute the less-expensive generic Namenda IR when presented with a prescription for Namenda XR. Such automatic substitution of less-expensive AB-rated generics at the pharmacy counter is the most efficient market means by which generic competition reduces drug prices. Forest's introduction of Namenda XR disrupted this normally occurring efficient competitive mechanism whereby consumers are afforded discounted prices at the expiration of exclusivity periods for branded drugs.

188. Defendants' exclusionary conduct has delayed, prevented, and impeded the sale of generic memantine hydrochloride in the United States, and unlawfully enabled Forest to sell significantly more branded memantine hydrochloride at artificially inflated prices. To the extent that Forest had any valid business purpose for the product hop to Namenda XR, that purpose is outweighed by the anticompetitive effects of the conduct. Forest's conduct had the intended effect of allowing it to maintain and extend its monopoly and exclude competition in the relevant

[46] *State of New York v. Actavis*, No. 14-4624, (2d Cir. May 28, 2015).

market, to the detriment of all memantine hydrochloride purchasers, including Plaintiff, members of the Class, and consumers. Accordingly, the anticompetitive effects of Forest's conduct clearly outweigh the purported procompetitive benefits (if any) of such conduct.

189. Similarly, Forest cannot justify its conduct with any supposed consumer benefit, as the enormous cost savings offered by generic drugs outweigh any supposed benefit from the new formulation of Namenda, which benefits are illusory. Forest's exclusionary motive is also illustrated by its willingness to sacrifice profits as part of the product hop strategy: Forest's decision to incur the extra costs necessary to change formulations was economically rational only if the change had the effect of excluding generic competition for Namenda IR. But for the impact on generic competition, Forest would not have invested the resources necessary to bring Namenda XR to the market. But for the impact on generic competition, it would not have been economically rational to invest in licensing the supposed extended-release technology, developing the interchangeable Namenda XR formulation, seeking FDA approval of that formulation, and changing the Namenda tablet manufacturing processes. The conversion from the original Namenda formulation to the new Namenda XR formulation reduced Forest's short term profits and made economic sense only because of the long term anticompetitive effects of obstructing generic challengers' most efficient means of competing.

190. Had Forest not forced the conversion of a substantial portion of the Memantine Hydrochloride Market to the new formulation prior to the entry of generic equivalents to Namenda IR, physicians and patients would have been able to weigh the relative medical benefits and prices of the two formulations, and would have been able to choose the formulation and price point they preferred. Forest introduced Namenda XR and took the actions described

above to with respect to discontinuing Namenda IR in order to deny consumers that choice and preserve its monopoly profits.

191. Had Forest not substantially converted the Memantine Hydrochloride Market to the Namenda XR formulation, a launch of AB-rated generic equivalent versions of Namenda IR would have quickly captured the bulk of memantine hydrochloride sales in the market. As a result, most, if not all, of the prescriptions that are now being filled with Namenda XR instead would have been filled with generic memantine hydrochloride.

192. Moreover, had generic Namenda IR launched before Namenda XR (as might have occurred but for the Contingent Entry Agreements), the generics would have quickly captured the bulk of brand Namenda IR sales, and the subsequent launch of Namenda XR (assuming it happened at all) would have had little effect on the sales of generic Namenda IR. As a result, generic Namenda IR would have captured the vast majority of the United States Memantine Hydrochloride Market and most, if not all, of the prescriptions that are now being filled with Namenda XR instead would have been filled with generic memantine hydrochloride.

VI. Class Allegations.

193. Direct purchaser plaintiff Smith Drug Company brings this action as a class action under Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of itself and as representative of a class defined as follows:

> All persons or entities in the United States and its territories who purchased branded Namenda IR 5 or 10 mg tablets, or Namenda XR capsules, directly from Forest or its successors in interest, Actavis and Allergan, at any time during the period from September 22, 2011 until the anticompetitive effects of Defendants' conduct cease (the "Class").

Excluded from the Class are the defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

194. Joinder of the members of the Class is impracticable. Plaintiff believes the Class members are numerous and widely dispersed throughout the United States. Further, the Class is readily identifiable from information and records in the possession of defendants. Direct notice to the members of the Class can be made upon obtaining the relevant information and records in the possession of defendants.

195. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by defendants' same wrongful conduct. Specifically, they paid artificially inflated prices for memantine hydrochloride and were deprived of the benefits of competition from and the choice of cheaper generic versions of Namenda IR as a result of the defendants' wrongful conduct.

196. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

197. Plaintiff and the Class are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

198. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in the defendants' wrongful conduct.

199. Questions of law and fact common to the Class include:

a. whether defendants conspired to restrain competition in the Memantine Hydrochloride Market;

b. whether Forest and/or Merz gave valuable consideration to the Potential First-Filing Generics in exchange for a delay in generic competition;

c. whether the contingent launch provisions of the Contingent Entry Agreements were necessary to yield some procompetitive benefit that is legally cognizable and nonpretextual;

d. whether Forest and/or Merz's coerced product hop from Namenda IR to Namenda XR was anticompetitive;

e. whether defendants' challenged conduct harmed competition in the Memantine Hydrochloride Market;

f. whether the Potential First Filing Generics would have prevailed in the underlying patent infringement litigation, launched "at risk," secured an earlier agreed entry date, or launched upon patent expiration absent the illegal settlements;

g. whether Forest possessed market power in the Memantine Hydrochloride Market;

h. whether the relevant antitrust market (if a relevant market must be defined) is the Memantine Hydrochloride Market;

i. whether defendants' activities alleged herein have substantially affected interstate commerce;

j. whether, and to what extent, defendants' conduct caused antitrust injury to the business or property of plaintiff and members of the Class in the nature of overcharges; and

k. the quantum of overcharges paid by plaintiff and the Class in the aggregate.

200. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining

redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

201. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VII. Market Power and Relevant Market

202. There is no cure for Alzheimer's disease. Patients and their loved ones depend on a handful of medications approved to treat the disease, hoping that the medications may be able to temporarily alleviate some systems or slow down the progression of others. Currently, five drugs are FDA approved for the treatment of Alzheimer's: Aricept, Cognex, Exelon, Razadyne, and Namenda. Cognex was withdrawn from the market in 2012 because it was toxic.

203. Aricept, Cognex, Exelon, and Razadyne are drugs known as acetylcholinesterase inhibitors ("AChEIs") and they all work in the same basic manner. AChEIs reduce the breakdown in the brain of a chemical called acetylcholine, a chemical messenger that transmits information between nerve cells. However, Alzheimer's destroys the cells that make acetylcholine, in turn making AChEIs less effective as the disease progresses.

204. Memantine, branded and marketed in the United States by Forest as Namenda, is an N-methyl-D-aspartate ("NMDA") receptor antagonist and functions differently than AChEIs. Essentially, Namenda works to prevent the overstimulation by glutamate, an amino acid that excites nerves, and in excess, is a powerful nerve-cell killer. Namenda is the only NMDA antagonist approved by the FDA for treatment of Alzheimer's in the United States, and has been approved for use in patients with moderate and severe Alzheimer's.

205. Namenda is not generally prescribed as a substitute for AChEIs. Instead, the drugs are usually prescribed together, or at different stages. About 70% of Alzheimer's patients

taking Namenda are taking an AChEI as well. Doctors commonly prescribe an AChEI first, and then Namenda is either added or patients are moved to Namenda when the disease has progressed to a moderate stage and AChEIs become ineffective. Although there is little clinical support for the use of Namenda for Alzheimer's patients in the early stages of the disease, some physicians will prescribe it in conjunction with an AChEI when the diagnosis is first made, relying on the fact that there are few significant adverse side effects associated with Namenda.

206. Defendants Forest and its successor Allergan (formerly Actavis), both experienced producers in the market, have premised their entire product hop strategy on the absence of substitutes for memantine. In January 2013, a Forest employee expressed confidence discontinuing Namenda would likely be successful because, unlike other attempts to pursue similar product extension strategies, "there are no alternatives" to Namenda – "although of course patients could simply stop taking the drug."[47]

207. At all relevant times, Forest had market power over memantine hydrochloride because Forest had the power to maintain the price of these products at supracompetitive levels without losing substantial sales to other daily pain management products. This market power may be shown directly, and therefore no relevant market needs to be defined.

208. To the extent a relevant product market must be defined, the relevant product market at issue in this case is formulations of memantine hydrochloride — which, as noted, currently includes only those drugs with memantine as their active ingredient. As described above, memantine has a unique mechanism of action and typically is used at different stages of the disease than AChEIs, the only other authorized treatment for Alzheimer's. The fact that these

[47] Presentation titled "Namenda IR & XR Conversion Plan." NYAG Opinion at p.47.

two classes of drugs are frequently prescribed together indicates that they are complements, not substitutes, and do not compete head to head. In fact, Forest intends to introduce a new drug that is a "fixed dose combination" of Namenda and an AChEI.

209. A small but significant, non-transitory price increase for memantine hydrochloride by Forest would not have caused a significant loss of sales to other medications sufficient to make such a price increase unprofitable.

210. Namenda IR does not exhibit significant, positive cross-elasticity of demand with respect to price, with any product other than AB-rated generic versions of Namenda IR.

211. Namenda IR is not reasonably interchangeable with any products other than AB-rated generic versions of Namenda IR. The FDA does not consider Namenda IR and other medications to be interchangeable.

212. Price does not drive prescriptions for Namenda IR or other Alzheimer's medications. The pharmaceutical marketplace is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Namenda IR, to patients without a prescription written by a doctor. This prohibition introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

213. Studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

214. Forest needed to control only Namenda IR and its AB-rated generic equivalents, and no other products, in order to maintain the price of Namenda IR profitably at supracompetitive prices. Only the market entry of a competing, AB-rated generic version of Namenda IR would render Forest unable to profitably maintain its current prices of Namenda without losing substantial sales.

215. The entry of other brands of Alzheimer's medications (or generic versions of those other brands) did not take substantial sales from Namenda IR or cause Forest to lower its price. By contrast, the competitive impact of an AB-rated generic version of Namenda IR on brand Namenda IR would be substantial. Among other things, the entry of an AB-rated generic Namenda IR would deliver hundreds of millions of dollars of savings to consumers.

216. At all relevant times, Forest has sold Namenda IR at prices well in excess of the competitive price.

217. At all relevant times, Forest had, and exercised, the power to exclude and restrict competition to Namenda IR and AB-rated bioequivalents.

218. At all relevant times, Forest enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

219. The relevant geographic market is the United States and its territories.

220. Forest's market share in the relevant market was either 100% or close to 100% at all relevant times.

VIII. Market Effects and Damages to the Class

221. But for the anticompetitive conduct alleged above, the Potential First-Filing Generics would have entered the market with their generic versions of Namenda IR many years ago – as early as when they began receiving final FDA approval of their generic equivalents.

Other generic manufacturers would have entered the market with additional generic versions of Namenda IR thereafter.

222. But for the anticompetitive conduct alleged above, Forest would likely not have introduced Namenda XR and would likely not have announced the discontinuation of Namenda IR, and this conversion of the market would not have significantly affected generic manufacturers' ability to penetrate the Memantine Hydrochloride Market with AB-rated versions of Namenda IR.

223. But for the anticompetitive conduct alleged above, Forest's efforts to switch the Market from Namenda IR to Namenda XR would not have significantly affected generics' ability to make sales of generic versions of Namenda IR because, absent the agreed-upon delay brokered by Forest and Merz, one or more of the Potential First-Filing Generics would have launched before Forest launched Namenda XR, and the vast majority, 90% or so, of the sales of Namenda IR would have switched to the generic product before the launch of Namenda XR (assuming it would have still launched at all) at prices below Namenda IR (or Namenda XR).

224. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Namenda IR from generic competition.

225. Each of the Potential First-Filing Generics has extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand.

226. Defendants' anticompetitive conduct, which delayed introduction into the United States marketplace of generic versions of Namenda IR, has caused plaintiff and the Class

to pay more than they would have paid for memantine hydrochloride absent defendants' illegal conduct.

227. Typically, generic drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, nearly all brand drug purchases are rapidly substituted for generic equivalents of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers.

228. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

229. But for defendants' anticompetitive conduct, plaintiff and members of the Class would have paid less for memantine hydrochloride by: (a) substituting purchases of less-expensive AB-rated generic Namenda IR for their purchases of more-expensive branded Namenda IR and/or Namenda XR; (b) receiving discounts on their remaining brand Namenda IR and/or Namenda XR purchases; and (c) purchasing generic Namenda IR at lower prices sooner.

230. Moreover, due to defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) launching generic versions of Namenda IR, and/or (b) challenging the validity or infringement of the '703 Patent in court.

231. Thus, defendants' unlawful conduct deprived plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

IX. Antitrust Impact

232. During the relevant period, plaintiff and members of the Class purchased substantial amounts of memantine hydrochloride directly from Forest. As a result of defendants' illegal conduct, plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for their memantine hydrochloride requirements. Those prices were substantially greater than the prices that plaintiff and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of memantine hydrochloride was artificially inflated by defendants' illegal conduct, and (2) plaintiff and Class members were deprived of the opportunity to purchase lower-priced generic versions of Namenda IR.

233. As a consequence, plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

X. Effect On Interstate Commerce

234. At all material times, Namenda IR (and Namenda XR), manufactured and sold by Forest and/or Actavis (now Allergan), was shipped across state lines and sold to customers located outside its state of manufacture.

235. During the relevant time period, in connection with the purchase and sale of Namenda IR (and Namenda XR), monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

236. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and

interstate and foreign telephone commerce. Defendants' activities were within the flow of, and have substantially affected, interstate commerce.

XI. Claims for Relief

Count 1: Monopolization in Violation of Section 2 of the Sherman Act, Unlawful Maintenance of Monopoly Power by Conversion of the Namenda Market from IR to XR Formulation. (Asserted Against Forest and its Successor, Actavis (now Allergan)) [48]

237. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

238. During the relevant period, Forest willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits, As explained in detail above, Forest unlawfully coerced the conversion of the Memantine Hydrochloride Market from Namenda IR to Namenda XR, which is not safer or more effective than Namenda IR by, *inter alia*, publicizing to doctors, caregivers and the general public that the discontinuation of Namenda IR was imminent, significantly limiting or attempting to limit the distribution of Namenda IR, and requesting that CMS remove Namenda IR tablets from the 2015 Formulary Reference File ("FRF").

239. The goal, purpose, and/or effect of Forest's conduct was to maintain and extend Forest's monopoly power with respect to memantine hydrochloride. Forest's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of competition from any generic version of Namenda, enabled Forest to continue charging supra-competitive prices for memantine hydrochloride without a substantial loss of sales.

[48] In all Claims for Relief, "Forest" includes successor entities Actavis and Allergan.

240. As a result of Forest's illegal conduct, Plaintiffs and the Class paid more than they would have paid for memantine hydrochloride, absent Forest's illegal conduct. But for Forest's illegal conduct, competitors would have begun marketing generic versions of Namenda well before they actually did, and/or would have marketed such versions more successfully than they actually did.

241. If manufacturers of generic memantine hydrochloride had been able to enter the market and fairly compete with Forest in a full and timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic Namenda IR for some or all of their memantine hydrochloride requirements, and/or would have received lower prices on some or all of their remaining branded Namenda purchases, at earlier periods of time and/or in far greater quantities.

242. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Namenda IR and Namenda XR directly from Forest. As a result of Forest's illegal conduct, alleged herein, Plaintiffs and the members of the Class were compelled to pay, and did pay, artificially inflated prices for their memantine hydrochloride requirements. Plaintiffs and all other Class members paid prices for memantine hydrochloride that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic memantine hydrochloride instead of expensive brand-name Namenda; and/or (b) the price of branded Namenda was artificially inflated by Forest's illegal conduct.

243. Forest's intentional conversion of the market from the IR to the XR formulation was an act of monopolization undertaken with the specific intent to monopolize the market for

memantine hydrochloride in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

Count 2: Monopolization in Violation of Section 2 of the Sherman Act, Unlawful Maintenance of Monopoly Power through an Overarching Scheme to Prevent or Delay Generic Competition. (Asserted Against Forest and its Successor, Actavis (now Allergan))

244. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

245. At all relevant times, Forest possessed monopoly power in the relevant market.

246. Forest, *inter alia*, marketed and sold the various versions of Namenda in the United States. During the relevant period, Forest willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Forest engaged in an exclusionary scheme that included, *inter alia*, the following independently-actionable, anticompetitive elements:

a. Creating a network of horizontal market-delay agreements among Forest and the Potential First-Filing Generics, all direct competitors, through the contingent launch provisions in the various Contingent Entry Agreements and/or paying the Potential First-Filing Generics large and unexplained amounts of cash or other consideration in exchange for their agreement to delay market entry;

b. Entering into non-compete agreements with the Potential First-Filing Generics that extended beyond the expiration of the '703 patent; and

c. Using the market delay created by the reverse payments and/or contingent entry agreements described above to implement a product hop scheme whereby Forest used various coercive tactics to deprive Alzheimer's

> patients and physicians of choice in the Memantine Hydrochloride Market and force the conversion of Namenda IR sales to the patent-protected Namenda XR prior to the launch of generic versions of Namenda IR.

247. The goal, purpose, and/or effect of Forest's scheme was to maintain and extend Forest's monopoly power in the Memantine Hydrochloride Market. Forest's illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic versions of Namenda IR enabled Forest to continue charging supracompetitive prices for memantine hydrochloride without a substantial loss of sales. If manufacturers of generic versions of Namenda IR had been able to enter the market and fairly compete with Forest in a full and timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic versions of Namenda IR for some or all of their memantine hydrochloride requirements, and/or would have received lower prices on some or all of their remaining branded memantine hydrochloride tablet purchases, at earlier periods of time and in far greater quantities.

248. As a result of the illegal scheme of Forest, Plaintiffs and the Class paid more than they would have paid for memantine hydrochloride, absent Forest's illegal conduct. But for Forest's illegal conduct, competitors would have begun marketing generic versions of Namenda IR well before they actually did, and/or would have marketed such versions more successfully

249. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Namenda IR (and Namenda XR) directly from Forest. As a result of Forest's illegal conduct, alleged herein, Plaintiffs and the members of the Class were compelled to pay, and did pay, artificially inflated prices for their memantine hydrochloride requirements. Plaintiffs and all other Class members paid prices for memantine hydrochloride that were substantially greater than the prices that they would have paid absent the illegal conduct alleged

herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic versions of Namenda IR instead of expensive brand-name Namenda IR (and Namenda XR); and/or (b) the price of branded Namenda was artificially inflated by Forest's illegal conduct.

250. Forest's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the Memantine Hydrochloride Market in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

Count 3: Monopolization in Violation of Section 2 of the Sherman Act, Unlawful Maintenance of Monopoly Power through an Agreement Not to Compete Beyond the Expiration of the '703 Patent. (Asserted Against Forest and its Successor, Actavis (now Allergan))

251. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

252. During the relevant period, Forest willfully and unlawfully maintained its monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits, As explained in detail above, Forest entered into license agreements with multiple would-be generic competitors that were illegal and independently anticompetitive in that they precluded generic competition for three months beyond the expiration of the '703 patent term (because pediatric exclusivity did not extend the patent term with respect to the subject generic challengers).

253. The goal, purpose, and/or effect of Forest's conduct was to maintain and extend Forest's monopoly power with respect to memantine hydrochloride. Forest's illegal conduct, calculated and designed to prevent, delay, and/or minimize the success of competition

from any generic version of Namenda, enabled Forest to continue charging supra-competitive prices for memantine hydrochloride without a substantial loss of sales.

254. As a result of Forest's illegal conduct, Plaintiffs and the Class paid more than they would have paid for memantine hydrochloride, absent Forest's illegal conduct. But for Forest's illegal conduct, competitors would have begun marketing generic versions of Namenda before they actually did, and/or would have marketed such versions more successfully than they actually did.

255. If manufacturers of generic memantine hydrochloride had been able to enter the market and fairly compete with Forest in a full and timely fashion, Plaintiffs and members of the Class would have substituted lower-priced generic Namenda IR for some or all of their memantine hydrochloride requirements, and/or would have received lower prices on some or all of their remaining branded Namenda purchases, at earlier periods of time and/or in far greater quantities.

256. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of Namenda IR and Namenda XR directly from Forest. As a result of Forest's illegal conduct, alleged herein, Plaintiffs and the members of the Class were compelled to pay, and did pay, artificially inflated prices for their memantine hydrochloride requirements. Plaintiffs and all other Class members paid prices for memantine hydrochloride that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic memantine hydrochloride instead of expensive brand-name Namenda; and/or (b) the price of branded Namenda was artificially inflated by Forest's illegal conduct.

257. Forest's illegal license arrangements were undertaken with the specific intent to monopolize the market for memantine hydrochloride in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT 4: VIOLATION OF 15 U.S.C. § 1
AGREEMENTS RESTRAINING TRADE
(Asserted Against All Defendants)

258. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

259. Defendants have engaged in continuing unlawful contracts, combinations, and conspiracies that have unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

260. The unlawful contracts, combinations, and conspiracies consist of Forest and Merz entering into the Contingent Entry Agreements with the Potential First-Filing Generics, under which Forest and the Potential First-Filing Generics, all direct competitors, created an inter-related network of horizontal market-delay agreements through the contingent launch provisions in each of the Contingent Entry Agreements. The purpose and effect of this conduct and these agreements were (and are) to: (a) allocate close to 100% of the Memantine Hydrochloride Market to Forest; (b) prevent the sale of generic versions of Namenda IR in the United States, thereby nearly completely protecting Namenda IR from generic competition for many years, during which time Forest could switch the Market to Namenda XR; and (c) fix, raise, maintain or stabilize the price at which direct purchasers would pay for Namenda or its AB-rated generic equivalents at supracompetitive levels.

261. Each Contingent Entry Agreement between the Defendants and each Potential First Filing Generic was independently anticompetitive and unlawful and further part of an overall conspiracy between and among the Defendants and the Potential First Filing Generics not to compete with each other.

262. The Contingent Entry Agreements harmed plaintiff and the Class as set forth above.

263. The Contingent Entry Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

264. The Contingent Entry Agreements, and the conduct of Forest and Merz under and pursuant to those agreements, constitute an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the contingent launch provisions of the agreements that outweighs their harmful effect. Even if there were some conceivable justifications, the contingent launch provisions were not necessary to achieve such a purpose, nor were they the least restrictive means of achieving any such purported justification.

265. As a direct and proximate result of the Defendants' anticompetitive conduct, as alleged herein, plaintiff and the Class have been harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

COUNT 5: VIOLATION OF 15 U.S.C. § 1
AGREEMENTS RESTRAINING TRADE
(Asserted Against All Defendants)

266. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

267. Defendants have engaged in continuing unlawful contracts, combinations, and conspiracies that have unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

268. The unlawful contracts, combinations, and conspiracies consist of Forest and Merz entering into the Contingent Entry Agreements with the Potential First-Filing Generics, which are independently anticompetitive horizontal market-allocation agreements insofar as they contain license provisions that precluded generic competition for three months beyond the expiration of the '703 patent term (because pediatric exclusivity did not extend the patent term with respect to the subject generic challengers).

269. The purpose and effect of this conduct and these agreements were (and are) to: (a) allocate close to 100% of the Memantine Hydrochloride Market to Forest; (b) prevent the sale of generic versions of Namenda IR in the United States, thereby nearly completely protecting Namenda IR from generic competition; and (c) fix, raise, maintain or stabilize the price at which direct purchasers would pay for Namenda or its AB-rated generic equivalents at supracompetitive levels.

270. Each Contingent Entry Agreement between the Defendants and each Potential First Filing Generic was independently anticompetitive and unlawful and further part of an overall conspiracy between and among the Defendants and the Potential First Filing Generics not to compete with each other.

271. The anticompetitive license provisions of the Contingent Entry Agreements harmed plaintiff and the Class as set forth above.

272. The anticompetitive license provisions of the Contingent Entry Agreements covered a sufficiently substantial percentage of the relevant market to harm competition.

273. The anticompetitive license provisions of the Contingent Entry Agreements between Forest/Merz and the Potential First-Filing Generics, and their conduct under and pursuant thereto, constitute an illegal restraint of trade or commerce and a continuing violation of the Sherman Act. There is and was no legitimate, nonpretextual, procompetitive business justification for the license provisions. Even if there were some conceivable justifications, the license provisions were not necessary to achieve such a purpose, nor were they the least restrictive means of achieving any such purported justification.

274. As a direct and proximate result of the Defendants' anticompetitive conduct, as alleged herein, plaintiff and the Class have been harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

XII. Demand for Judgment

WHEREFORE, Smith Drug Company, on behalf of itself and the Class, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare Smith Drug Company a representative of the Class;

B. Enter joint and several judgments against the defendants and in favor of Smith Drug Company and the Class;

C. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

D. Award Smith Drug Company and the Class their costs of suit, including reasonable attorneys' fees as provided by law.

XIII. Jury Demand

Pursuant to Federal Rule of Civil Procedure 38, Smith Drug Company, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: October 13, 2015

Respectfully submitted,

/s/ Bruce E. Gerstein

Bruce E. Gerstein
(Attorney Bar Code #2726)

GARWIN GERSTEIN & FISHER LLP
Bruce E. Gerstein
Joseph Opper
Noah Silverman
88 Pine Street, 10th Floor
New York, NY 10005
Tel: (212) 398-0055
Fax: (212) 764-6620
bgerstein@garwingerstein.com

SMITH SEGURA & RAPHAEL, LLP
David C. Raphael, Jr.
Erin R. Leger
3600 Jackson Street, Suite 111
Alexandria, LA 71303
Tel: (318) 445-4480
Fax: (318) 487-1741
draphael@ssrllp.com

ODOM & DES ROCHES, L.L.P.
Stuart E. Des Roches
Andrew W. Kelly
650 Poydras Street, Suite 2020
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078
stuart@odrlaw.com

HEIM PAYNE & CHORUSH, LLP

Russ Chorush
Miranda Jones
600 Travis, Suite 6710
Houston, TX 77002
Tel: (713) 221-2000
Fax: (713) 221-2021
rchorush@hpcllp.com

Counsel for J M Smith Corporation d/b/a Smith Drug Company and the Proposed Class